

#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

#### **Selection Criteria:**

Product Name:	[EPIPEI	N,EPIPEN JR]		
Product Active Ingredient:				
Active Ingredient:				
Active Moiety:				
FDA Received Date:	From:	01-Jan-2012	To:	15-May-2018
MedDRA® Version*:	21.0			
Total Cases**:	2114			
Number of Pages:	533			

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

<sup>\*. &</sup>quot;MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

<sup>\*\*. &</sup>quot;Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.



The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting.  Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers.
Health Prof	Indicates whether the initial source who provided information about the event is a health professional. Possible values are; Y - Yes, N – No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Mfr Control #	The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.
503B Facility	Indicates whether the organization that sent the report to FDA is an outsourcing facility. An outsourcing facility is a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the Food, Drug, and Cosmetic Act. Possible value is Y – Yes.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).

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Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products.
Product	Name of a drug or biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Comp.	Indicates whether the suspect product is a compounded drug, as identified in the report. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Possible value is Y – Yes.
ОТС	Indicates whether the suspect product is an over-the-counter (OTC) drug, as identified in the report. OTC drug products are those drugs that are available to consumers without a prescription. Possible value is Y – Yes.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Mfr	The manufacturer of the product, as indicated in the report.

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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jan-2012	8304794	NON-EXPEDITED	N			US-PFIZER INC K201100543	<b>&gt;-</b>	51 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u> <u>Mfr</u>		
Drug Ineffective	Epipen				S		Unk		Pfi	zer
	Tramad	ol			С		50 Mg, Every 4 Hours As Needed			
	Flexeril				С		5 Mg, As Needed			
	Zoloft				С	Occlusive dressing technique	100 Mg, 1x/Day			
	Valium				С	Oral	5 Mg, As Needed			
	Hydroco	odone			С	Oral	Unk			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jan-2012	8373376	DIRECT							Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Intercepted Drug	Epipen	Jr			S		Injection			
Dispensing Error; Medication Error	Epipen				S		Auto-Injection			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jan-2012	8323230	EXPEDITED (15-DAY)	N		ОТ	GB-PFIZER IN 2012002140	>-	72 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Epipen Chest Pain; Dyspnoea; ncorrect Route Of Drug Administration				S	Intravenous (not otherwise specified)	Unk		Pfi	zer	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2012	8281347	NON-EXPEDITED	N		ОТ	US-PFIZER INC 2011298135	<b>&gt;</b> -	23 YR	Female	USA



Preferred Term	Product	:	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Drug Ineffective; Dyspnoea	Epipen				S		Unk		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr C	ontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Feb-2012	8322241	NON-EXPEDITED	Υ			US-PF 20113	TIZER INC- 15825		Male	USA
Preferred Term	Product		Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	• -
Drug Ineffective	Epipen				S				Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr C	ontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Feb-2012	8338948	NON-EXPEDITED	Υ			US-PF 20120	IZER INC- 06892		Male	USA
Preferred Term	Product		Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Injury Associated With Device	Epipen				S				Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr C	ontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2012	8320098	EXPEDITED (15-DAY)	Υ	(	ОТ		IZER INC- 14930		Male	CAN
Preferred Term	Product	:	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Contusion; Expired Product Administered; Injection Site Coldness; Injection Site Pallor; Pain	1				S				Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr C	ontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Feb-2012	8326303	NON-EXPEDITED	Υ			US-PF 20120	FIZER INC- 02151		Female	USA
Preferred Term	Product	:	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mfr	:
Accidental Exposure T Product; Injury Associa					S				Pfi	zer

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FDA Received Date	Case #	Case Type	Hoalth	Prof O	utcomes	Mfr Contro	.1.# 50	3B Facility	Ago	Sex	Country
06-Feb-2012	8327922	NON-EXPEDITED	Y	<u> </u>	<u>utcomes</u>	US-PFIZER 2012002472	INC-	<u>зв гасшіў</u>	<u>Age</u>	Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Tex	<u>xt</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipe	en			S					Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Feb-2012	8350290	NON-EXPEDITED	N			US-PFIZER 2012017040				Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>xt</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injury Associa With Device		en Jr			S					Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Feb-2012	8384238	NON-EXPEDITED	N			US-PFIZER 2011307739				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>xt</u>	<b>Duration</b>	Mfr	
Injury Associated With Device	n Epipe	en			S					Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2012	8422150	DIRECT	N						5 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>xt</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Failt Of Child Resistant Mechanism For Pharmaceutical Produ Foreign Body; Injury Associated With Device	ure	en			S					Dey	(



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Feb-2012	8281358	NON-EXPEDITED	Υ	0	Γ	US-PFI2 201129	ZER INC- 3125		22 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfı</u>	<u>r</u>
Drug Ineffective	Epipei	า	S				Unk			Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Feb-2012	8387834	NON-EXPEDITED	N			US-PFI2 201202	ZER INC- 7939			Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfı	<u>.</u>
Accidental Exposure T Product; Feeling Jitter		1			S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Feb-2012	8387846	NON-EXPEDITED	N			US-PFI2 201202	ZER INC- 7833			Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfı</u>	<u>.</u>
Accidental Exposure T Product; Hyperhidrosis Injection Site Discomfo Injection Site Mass; Nausea; Nervousness Tremor	s; ort;	า			S		Unk			Pfi	izer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Feb-2012	8390762	NON-EXPEDITED	N			US-PFI2 201202	ZER INC- 7983			Male	USA
Preferred Term	Produ	ı <u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfı	1
Accidental Exposure T Product; Injection Site Pain; Injury Associated With Device		า			S					Pf	izer



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
28-Feb-2012	8407209	NON-EXPEDITED	Y	0	Γ	US-PFIZ 2012030	-		5 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Injury Associa With Device		n			S		0.3 M	ll, Unk	1 DAY	P	fizer
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Cor	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Feb-2012	8431595	NON-EXPEDITED	N			US-PFIZ 2012047	-		50 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Injection Site Discomfo Injury Associated With Device		n			S		Unk			P	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
29-Feb-2012	8429524	NON-EXPEDITED	Υ			US-PFIZ 2012049	-			Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Injury Associa With Device		n			S		Unk			P	fizer
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Cor	ntrol#	503B Facility	Age	Sex	Country
08-Mar-2012	8424959	EXPEDITED (15-DAY)	Υ	0	Γ	US-PFIZ 2012047	-			Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	Mf	<u>'r</u>
Accidental Exposure T Product; Injury Associa With Device		n			S		0.3 M	lg, Unk	1 DAY	P	fizer



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>/ Age</u>	<u>Sex</u>	Country
13-Mar-2012	8408287	EXPEDITED (15-DAY)	Υ	0	Γ	US-PFIZER INC- 2012037013		45 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure To Product; Expired Product Administered; Injection Site Anaesthesia; Injection Site Discolouration; Injunctions Injunction	uct ction ury				S				Pi	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Mar-2012	8438398	NON-EXPEDITED	N			US-PFIZER 201204567		18 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Injury Associated With Device					S		.3 Mg, As Needed		Pi	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2012	8428488	EXPEDITED (15-DAY)	Υ	0	Γ	US-PFIZER 201204579			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure To Product; Injury Associa With Device					S		0.3 Mg, Single	1 DAY	Pi	fizer
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Mar-2012	8384247	NON-EXPEDITED	Υ			US-PFIZER 2012023029		73 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Cyanosis; Injury Associated With Device Peripheral Coldness; Tremor	Epipen e; Epipen				S S					fizer fizer



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FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
21-Mar-2012	8470507	EXPEDITED (15-DAY)	Y	ŀ	НО	CH-PFIZER 201207125			8 YR	Male	CHE
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Cyanosis; Drug Administration Error; njection Site Pain	Epipen .	Jr			S	Subcutaneous	15 Mg	g, 1x/Day Total	1 DAY		Pfizer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Mar-2012	8388739	EXPEDITED (15-DAY)	N	(	OT	US-PFIZER 2012027869				Female	USA
referred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosag	e Text	<b>Duration</b>		<u>Mfr</u>
Blood Pressure Increa Loss Of Personal Independence In Daily Activities					S		Unk				Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Mar-2012	8472759	EXPEDITED (15-DAY)	Y	(	OT	AT-PFIZER 2012068000	-		37 YR	Male	AUT
referred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
accidental Exposure T Product; Application S Pallor; Bradycardia; Pizziness; Pain In Extremity; Pallor					S						Pfizer
DA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Mar-2012	8475387	NON-EXPEDITED	N			US-PFIZER 201207357				Male	USA
referred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>		<u>Mfr</u>
Accidental Exposure T Product	o Epipen				S						Pfizer



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FDA Received Date	Case #	Case Type	<b>Health</b>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
30-Mar-2012	8465258	EXPEDITED (15-DAY)	N		ОТ	US-PFIZER 2012067147	INC-			Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Hypoaesthesi Peripheral Coldness; S Discolouration	ia;				S		0.3 1	Mg, Unk	365 DAY	Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2012	8478814	EXPEDITED (15-DAY)	N		ОТ	US-PFIZER 2012073367				Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	-
Accidental Exposure T Product; Skeletal Injury					S					Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Apr-2012	8475392	NON-EXPEDITED	Υ			US-PFIZER 2012073699	-			Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	Mfr	
Vasoconstriction	Epipen				S					Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2012	8500962	NON-EXPEDITED	N			US-PFIZER 2012085248				Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Expired Produ Administered; Hypoaesthesia					S					Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2012	8503584	EXPEDITED (15-DAY)	Υ		ОТ	JP-PFIZER I 2012087213	-		41 YR	Male	JPN

Note: If the field is blank, there is no data.

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Preferred Term	Produc	<u> </u>	Comp.	OTC	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>Mf</u> ı	[
Hypertension; Loss Of Consciousness	Epipen Claritin				s C	Intramuscular Oral	0.3 Mg D 10 Mg, Q		1 DAY	Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol # <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Apr-2012	8507247	EXPEDITED (15-DAY)	N	H	Ю	GB-PFIZER 201208717			42 YR	Female	GBR
Preferred Term	Produc	<u>I</u>	Comp.	OTC	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfı</u>	
Accidental Exposure T Product; Application Si Pain; Pain In Extremity	ite				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contr	<u>ol #</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2012	8486214	NON-EXPEDITED	Υ			US-PFIZER 201207939				Female	USA
Preferred Term	Produc	<u>I</u>	Comp.	OTC	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	<u>Mfı</u>	<u>.</u>
Contusion; Pain; Swell	ing Epipen				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol # <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2012	8449370	NON-EXPEDITED	Υ			US-PFIZER 201205654			71 YR	Female	USA
Preferred Term	Produc	<u>I</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfı</u>	<u>:</u>
Accidental Exposure T Product; Injury Associa With Device; Ligament Injury; Pain In Extremit	ated				S	Intramuscular				Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 5	03B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2012	8486203	EXPEDITED (15-DAY)	Υ	C	DΤ	US-PFIZER 201207944			54 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>Mfı</u>	<u>.</u>
Accidental Exposure To Epipen Jr					S						izer

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#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product; Expired Product Administered; Skin Discolouration; Swelling

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2012	8492500	NON-EXPEDITED	N			US-PFIZ 2012077	ER INC- '157		16 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Expired Prod Administered; Pain In Extremity; Skin Discolouration		า			S					Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
02-May-2012	8234966	NON-EXPEDITED	N			US-PFIZ 2011261	ER INC- 190			Female	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<u>Duration</u>	Mfr	
Application Site	Epiper	n			S		0.3	Mg, Unk		Pfi	zer
Haematoma; Drug Ineffective; Expired	Twinje	ect			S		Unk	-			
Product Administered	Maxai	r			С						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-May-2012	8521038	NON-EXPEDITED	N			US-PFIZ 2012092	ER INC- 1630			Female	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<u>Duration</u>	Mfr	:
Application Site	Epiper	n			S		Unk	ζ.		Pfi	zer
Haematoma; Expired Product Administered	Twinje	ect			S		Unk	(			
r roddet Administered	Maxai	r			С		Unk	ζ.			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-May-2012	8518950	NON-EXPEDITED	Y			US-PFIZ 2012092	ER INC- 2413			Female	USA

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# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage</u>	<u>e Text</u>	<b>Duration</b>	<u>Mf</u> ı	• •
Accidental Exposure T Product; Expired Prod Administered; Pain In Extremity	oduct n				Pf	zer					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
09-May-2012	8372110	NON-EXPEDITED	N			US-PFIZ 2012019	ZER INC- 9541		35 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u> ı	:
Accidental Exposure T Product; Feeling Abnormal; Feeling Jitte	• •	n Jr			S		Unk			Pf	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2012	8494993	NON-EXPEDITED	N	0	Т	US-PFIZ 201208	ZER INC- 1547			Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mf</u> ı	
Accidental Exposure T Product; Dizziness; Hypoaesthesia	Го Еріреі	า			S		Unk		1 DAY	Pf	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-May-2012	8497079	NON-EXPEDITED	N			US-PFI2 2012082	ZER INC- 2741		32 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mf</u> ı	
Accidental Exposure T Product; Contusion; Feeling Abnormal; Injection Site Pain	Го Еріреі	1			S		Unk			Pf	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-May-2012	8521035	NON-EXPEDITED	Υ			US-PFI2 201209	ZER INC-		17 YR	Female	USA



Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Feeling Jitter Heart Rate Increased; Hypertension; Pallor	y;				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2012	8554843	NON-EXPEDITED	N			US-PFIZ 2012107	ER INC- 676		67 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Injectior Site Haemorrhage	uct Eninen				S S		Unk Unk			Pfi: Pfi:	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2012	8522978	EXPEDITED (15-DAY)	N			US-PFIZ 2012093	ER INC- 900			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Pain In Extremity					S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
											CAN
21-May-2012	8559850	EXPEDITED (15-DAY)	N			CA-PFIZ 2012112	ER INC- 009			Female	OAN
21-May-2012 Preferred Term	8559850 <u>Product</u>	,	N Comp.	<u>otc</u>	Role			e Text	<u>Duration</u>	Female <u>Mfr</u>	
Preferred Term		,		OTC	Role S	2012112	009	e Text	<u>Duration</u>		
Preferred Term	Produc	,	Comp.			2012112	Dosage Unk	e Text  503B Facility	<u>Duration</u>	<u>Mfr</u>	
Preferred Term  No Adverse Event	Product Epipen	<u>t</u>	Comp.	Prof C	S	2012112 <u>Route</u>	Dosage Unk  http://doc.			<u>Mfr</u> Pfi	zer

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Abnormal Loss Of Weight; Body Height Decreased;	Remicad	le			S	Intravenous (not otherwise specified	1)				
Cholelithiasis; Drug Ineffective; Food Allergy; Juvenile Idiopathic	Remicad	le			S	Intravenous (not otherwise specified	Also R	eported As Every 6			
Arthritis; Lipoma; Maternal Exposure During	Remicad	le			S	Intravenous (not otherwise specified	•				
Pregnancy; Nephrolithiasis; Tendon	Morphine	Э			S	Unknown					
Disorder	Fexofena	adine			S	Oral					
	Imuran				S	Unknown					
	Benadry			Υ	S	Oral					
	Epipen				S	Intramuscular					
	Solu-Me	drol			S	Unknown					
	Benadry			Υ	S	Unknown					
	Calcium	With Vitamin D			С	Oral					
FDA Received Date Case	<u> </u>	Case Type	Health	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2012 85538	822	EXPEDITED (15-DAY)	Υ	0	Т	GB-PFIZER II 2012112110	NC-			Male	GBR
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure To Product; Discomfort; Expired Product Administered; Injection Site Discomfort	Epipen				S		Unk			Pf	izer
FDA Received Date Case	<u> </u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
05-Jun-2012 85558	862	EXPEDITED (15-DAY)	Υ	0	Т	GB-PFIZER II 2012112084	NC-		29 YR	Female	GBR
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mf	<u>r</u>
Hypoaesthesia; Injection Site Haematoma; Injury Associated With Device	Epipen				S					Pf	izer



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Conti	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2012	8552687	EXPEDITED (15-DAY)	Υ		ОТ	US-PFIZEF 201211092	-		46 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	<u>ige Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pain; Injury Associated With Device; Periphera Ischaemia	d				S		0.3	Mg, Single		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2012	8570253	NON-EXPEDITED	N		ОТ	US-PFIZEF 201211813			53 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosa	<u>ige Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Heart R Increased; Swelling	uct				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2012	8568667	NON-EXPEDITED	Υ		ОТ	US-PFIZEF 201211657	-			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosa	<u>ige Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipen .	Jr			S		Stre	ength: 0.15 Mg		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2012	8580100	EXPEDITED (15-DAY)	Υ		ОТ	US-PFIZEF 201212363			35 YR	Female	USA
Preferred Term	<u>Produc</u>	<u>t</u>	Comp.	OTC	Role	Route	Dosa	<u>ige Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Blood Pressu Increased; Injury Associated With Device	re				S		0.3	Mg, Single		Pfi	zer

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Skin Discolouration;

racn	ycardia
EDA	Doooly

Tachycardia											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jun-2012	8627518	NON-EXPEDITED	N			US-PFIZER 2012126186	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>r</u>
No Adverse Event	Epipen				S		0.3 M	lg Unk		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2012	8604183	NON-EXPEDITED	N			US-PFIZER 2012132415	-		3 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>r</u>
Accidental Exposure T Product; Crying	Γο Epipen				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2012	8576410	EXPEDITED (15-DAY)	Υ	0	T	US-PFIZER 2012122450	-		40 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>ge Text</u>	<b>Duration</b>	<u>Mf</u> ı	<u>r</u>
Accidental Exposure T Product; Hypoaesthes Injection Site Pain; Injection Site Pallor; Muscular Weakness; Neuralgia					S	Intramuscular	Unk		1 DAY	Pfi	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2012	8559849	EXPEDITED (15-DAY)	N	0	Т	CA-PFIZER 2012111189	-			Male	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>r</u>
Accidental Exposure T Product; Product Qual Issue; Seizure					S		Unk			Pf	izer

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr C	Sontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2012	8587238	NON-EXPEDITED	Υ				FIZER INC- 27062		Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Drug Ineffective	Epipen	1			S		0.3 Mg, Unk		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr C	control # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2012	8613794	NON-EXPEDITED	N		ОТ		FIZER INC- 38439		Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen	1			S		0.3 Mg, Unk		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr C	control # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2012	8492106	NON-EXPEDITED	N		ОТ		IJFOC- 314657		Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Dizziness; Drug	Benad	ryl		Υ	S	Oral				
Ineffective; Extrasystologedema Peripheral;	es; Zyrtec			Υ	S	Oral				
Product Quality Issue	Zyrtec				S	Oral	11-12 Years			
	Epipen	ı			S	Unknown	11-12 Years			
	Unspe Meds	cified Blood Pressure			С	Unknown				
		er Therapeutic Products			С	Unknown				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr C	control # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2012	8611242	EXPEDITED (15-DAY)	N		ОТ		FIZER INC- 36148	15 YR	Female	CAN
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Anaphylactic Reaction; Drug Ineffective; Produ Quality Issue		ı			S		Unk	1 DAY	Pfiz	er

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							-				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2012	8621196	NON-EXPEDITED	N	0	Γ	US-PFI 201214	ZER INC- 2520			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Poor Periphe Circulation		n			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2012	8632228	EXPEDITED (15-DAY)	N	0	Γ	GB-PFI 201215	ZER INC- 0781			Female	GBR
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Heart Rate Increased; Loss Of Consciousness	o Epipe	n			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2012	8621214	NON-EXPEDITED	N	0	Γ	US-PFI2 201214:	ZER INC- 2542		67 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site Anaesthesia; Pallor	o Epipe	n Jr			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2012	8658854	NON-EXPEDITED	N			US-PFI 201216	ZER INC- 2598			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Circumstance Or Information Capable C Leading To Medication Error; Product Packag Issue	1	n			S		Unk			Pfi	zer

Note: If the field is blank, there is no data.

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
03-Aug-2012	8660195	NON-EXPEDITED	N			US-PF 201216	ZER INC- 3758			Unknown	USA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Pain	Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2012	8662554	NON-EXPEDITED	N			US-PF 201216	ZER INC- 3790		25 YR	Unknown	USA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pallor	o Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2012	8662572	NON-EXPEDITED	N			US-PF 201216	ZER INC- 3788			Unknown	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Therapeutic Response Jnexpected	Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2012	8704920	EXPEDITED (15-DAY)	N	I	LT	GB-PF 201212	ZER INC- 6190		20 YR	Female	GBR
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Device Fa	ilure Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	Sex	Country
06-Aug-2012	8662563	NON-EXPEDITED	N			US-PF 201216	ZER INC- 3763			Unknown	USA
Preferred Term	Product	•	Comp.	OTC	Role	Route	Dosage	o Toyt	<b>Duration</b>	<u>Mfr</u>	



Injection Site Pain	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cor	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2012	8660878	EXPEDITED (15-DAY)	Y	Н	)	GB-PFIZ 2012163	_			Female	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure; Injection Site Injury	on Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2012	8710714	NON-EXPEDITED	N			US-PFIZ 2012174	_			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Accidental Exposure T	Γο Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
16-Aug-2012	8679134	NON-EXPEDITED	Υ	0.	Т	US-PFIZ 2012172			23 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Expired Prod Administered; Injection Site Discolouration; Pa	luct n				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Aug-2012	8714472	NON-EXPEDITED	N			US-PFIZ 2012190	_		47 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Injection Site Pain					S		Unk			Pfi	zer

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Aug-2012	8569593	EXPEDITED (15-DAY)	N	ŀ	НО	GB-PFIZER 2012120164	-		3 YR	Female	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contusion	Epipen				S	Intramuscular	Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u> Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Aug-2012	8631248	EXPEDITED (15-DAY)	Υ	(	DΤ	US-PFIZER 2012146250	-		19 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective; Pharyngeal Oedema	Epipen				S		0.3 M	g, As Needed		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Aug-2012	8715134	EXPEDITED (15-DAY)	N	(	DΤ	US-PFIZER 2012190459			55 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Hand Fractur Heart Rate Increased; Hypoaesthesia; Injectio Site Pallor; Nail Bed Bleeding	e;				S	Intramuscular	0.3 M	g, Unk		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contro	1#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Aug-2012	8734882	NON-EXPEDITED	N			US-PFIZER 2012199682				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Circumstance Or Information Capable O Leading To Medication Error; Drug Ineffective					S		Unk			Pfi	zer



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Aug-2012	8632513	NON-EXPEDITED	Υ	(	DΤ	US-PFIZER II 2012148599	NC-	52 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Drug Ineffective; Produ Colour Issue	ict Epipen Epipen				S S	Intramuscular	0.3 Mg/0.3 Ml, Prn			izer izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Aug-2012	8750580	DIRECT	Υ	(	OT			78 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Malfunction	Epipen				S		0.3ml As Needed By Injection		D	еу
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Aug-2012	8729768	EXPEDITED (15-DAY)		(	TC	NL-PFIZER IN 2012198492	NC-	69 YR	Male	NLD
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Circulatory Collapse; Device Failure; Underd	Simvas	tatin pril Erbumine			S C C C		1 Df, 1x/Day 4 Mg, 1x/Day		Pf	fizer
	Ascal C	ardio			С	Oral	100 Mg, 1x/Day			
	Metforn	nin			С		500 Mg, 3x/Day			
	Alutard	Sq "Alk"			С		According To Scheme			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Sep-2012	8695683	EXPEDITED (15-DAY)		(	OT	US-PFIZER II 2012181556	NC-	1 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>

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Injection Site Bruising; Injection Site Injury; Injection Site Pain; Product Quality Issue	Epipen	Jr			S		Unk			Pf	izer .
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	Sex	Country
04-Sep-2012	8702522	NON-EXPEDITED				US-PFIZ 2012183			50 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Injection Site Discolouration					S		Unk			Pf	üzer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Cor	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
07-Sep-2012	8721391	EXPEDITED (15-DAY)		0	Т	US-PFIZ 2012195			41 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Hypoaesthes Pain In Extremity					S		Unk	%, Unk		Pf	iizer .
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Sep-2012	8762865	NON-EXPEDITED		0	Т	US-PFIZ 2012210	-			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	Mf	<u>r</u>
Drug Administration E Drug Ineffective; Dyspnoea	rror; Epipen				S		Unk			Pf	iizer .
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Sep-2012	8763990	EXPEDITED (15-DAY)		0	Т	US-PFIZ 2012211			79 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Blood Pressu		Epipen Jr S		S	Unk			Pfizer			



Increased; Tachycardia	a										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Sep-2012	8721733	NON-EXPEDITED				US-PFIZE 20121922	-		91 DAY	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	<u>ge Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Haemorrhage	o Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Sep-2012	8713951	EXPEDITED (15-DAY)			ОТ	CA-PFIZE 20121868	-		5 YR	Male	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Injection Site Laceration Product Quality Issue	on; Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Sep-2012	8790451	DIRECT			НО				42 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	отс	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Injury Associated With Device; Product Label Issue; Wrong Techniqu In Product Usage Proc	ue				S			ration Date 1/2010		De	у
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Sep-2012	8778738	NON-EXPEDITED				US-PFIZE 20121972				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
No Adverse Event	Epipen				S		Unk			Pfi	zer



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u> Οι	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Sep-2012	8726428	NON-EXPEDITED		ОТ	-	US-PFIZER II 2012195892	NC-	67 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Drug Ineffective; Produ Quality Issue	uct Epipe Epipe				S S		0.3 Mg/Ml			zer zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Sep-2012	8731238	NON-EXPEDITED		01	-	US-PFIZER II 2012197252	NC-	14 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Drug Ineffective; Produ	ıct Epipe	en			S	Intramuscular	0.3 MI, As Needed		Pfi	zer
Quality Issue	Epipe Accol				S C	Oral	Unk		Pfi	zer
	Duler	a			С	Nasal	Unk			
	Qvar				С	Nasal	Unk			
	Vento	olin			С	Nasal	Unk			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Sep-2012	8676361	NON-EXPEDITED		ОТ	-	US-PFIZER II 2012172076	NC-	31 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Drug Ineffective; Need	le Epipe	en			S		Unk		Pfi	zer
Issue	Buspi	irone			С	Oral	5 Mg, 3x/Day			
	Buspi Fluox				C C	Oral	40 Mg, 2x/Day			
	Fluox Metfo				C C	Oral	500 Mg, 2x/Day			
	Ambi	en			С	Oral	10 Mg, 1x/Day			
		amide			С	Oral				



						Dotalloa Itt	Sport			
	Calciu	m			С	Oral	Unk Qd			
	Magne	esium			С	Oral	Unk Qd			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2012	8725471	EXPEDITED (15-DAY)			НО	US-PFIZER IN 2012198571	IC-	38 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	<u>.</u>
Acute Myocardial	Epiper	1			S	Intramuscular	0.3 Mg, Single		Pf	izer
Infarction	Solu-M	ledrol			С	Intravenous (not otherwise specified	125 Mg, Single )			
	Zofran				С	Intravenous (not otherwise specified	4 Mg, Single )			
	Benad	ryl			С	Intravenous (not otherwise specified	50 Mg, Single )			
	Ativan				С	Intravenous (not otherwise specified	1 Mg, Single )			
	Zantad				С	Intravenous (not otherwise specified	50 Mg, Single )			
	Combi	vent			С	Respiratory (inhalation)	Two Nebuliser Treatment	ts		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2012	8761379	EXPEDITED (15-DAY)			ОТ	US-PFIZER IN 2012207673	IC-	2 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	<u>-</u>
Crying; Injury Associat With Device; Pain	ed Epiper	ı Jr			S		Unk		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Sep-2012	8762641	NON-EXPEDITED				US-PFIZER IN 2012206273	IC-		Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	
Musculoskeletal Stiffne	ess Epipen	1			S				Pf	izer

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Sep-2012	8738724	EXPEDITED (15-DAY)		0	Т	US-PFI 201220	ZER INC- 3447		36 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mf</u> ı	<u>r</u>
Accidental Exposure T Product; Contusion; Hypoaesthesia; Pain	o Epipe	en			S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Sep-2012	8815122	NON-EXPEDITED				US-PFI 201224	ZER INC- 0473			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mfı</u>	<u>r</u>
No Adverse Event	Epipe	en			S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Oct-2012	8821743	EXPEDITED (15-DAY)		0	Т		507513- SA000708			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>r</u>
Condition Aggravated;	Janur	met			S	Oral	50m	g/500mg,Qd		Me	erck
Memory Impairment; Myocardial Infarction	Zocoi	r			S	Oral				Me	erck
,	Diova	an			S	Oral	160	Mg, Qd			
	Metfo	ormin			S	Oral	500	Mg, Qd			
	Nitrol	ingual			S		0.4	⁄/Jg, Prn			
	Zyrte	С			S	Oral	10 M	lg, Qd			
	Gaba	pentin			S	Oral	2 Df	Tid			
	Vicod	lin			S	Oral	1 Df	, Q4h			
	Bupro	ppion Hydrochloride			S	Oral	300	Mg, Qd			
	Lozol				S	Oral	1.5 [	Иg, Qd			
	Klond	ppin			S	Oral	0.5	Иg, Bid			
	Prilos	sec			S	Oral	20 N	lg, Bid			

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						Dotalioa	(opert			
		Carafate			S	Oral	1 G, Bid			
		Aggrenox			S	Oral	Unk, Bid			
		Flonase			S	Nasal	4 Df, Qd			
		Flovent			S		2 Df, Bid			
		Ventolin (Albuterol)			S		2 Df, Q2h			
		Imitrex (Sumatriptan Succinate)			S	Oral	100 Mg, Prn			
		Epipen			S	Transdermal				
		Lortab			S	Oral				
		Vitamins (Unspecified)			S					
		Zanaflex			S	Oral	2 Mg, Bid			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Oct-2012	882175	66 EXPEDITED (15-DAY)		(	T	US-MERCK 1210USA00			Female	USA
Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Anxiety; Arterial Disord	der;	Janumet			S	Oral			Me	erck
Arthralgia; Asthma; Cardiac Disorder;		Zocor			S	Oral			Me	erck
Condition Aggravated;		Aggrenox			S	Oral				
Depression; Diabetes Mellitus; Diabetic		Gabapentin			S	Oral				
Neuropathy; Fibromya		Vicodin			S	Oral				
Gastrooesophageal Ro Disease; Memory	eflux	Zanaflex			S	Oral	4 Mg, Unk			
Impairment; Muscle		Valsartan			S	Oral	160 Mg, Unk			
Spasms; Panic Attack		Bupropion Hydrochloride			S	Oral	300 Mg, Unk			
		Lozol			S	Oral	1.25 Mg, Unk			
		Metformin			S	Oral	500 Mg, Unk			
		Klonopin			S	Oral	1 Mg, Unk			
		Prilosec			S	Oral	40 Mg, Unk			
		Carafate			S	Oral	2 G, Unk			
		Flonase			S	Respiratory (inhalation)				



		Flovent				S			440 Microgram, Unk			
			(Albuterol Sulfate) Sumatriptan Succinate)			S S	Oral					
		Nitrolingu Epipen	ual			S S	Transderm	al				
		Lortab				S	Oral	ui				
			(Unspecified)			S	Oral					
		Zyrtec	,			S	Oral		10 Mg, Unk			
FDA Received Date	Case	<u>#</u>	Case Type	<u>Health</u>	Prof	Outcomes	Mfr (	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Oct-2012	88234	83	EXPEDITED (15-DAY)			ОТ		IERCK- USA000868	3	55 YR	Female	USA
Preferred Term		Product		Comp.	<u>OTC</u>	Role	Route	<u> </u>	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Cardiac Disorder; Mer	mory	Januvia				S	Oral				Me	erck
npairment		Bupropio	n Hydrochloride			S	Oral		300 Mg, Qd			
		Vitamins	(Unspecified)			S	Oral					
		Gabapen	ntin			S	Oral		2 Df, Tid			
		Vicodin				S	Oral					
		Zanaflex				S	Oral		2 Mg, Bid			
		Diovan				S	Oral		160 Mg, Qd			
		Lozol				S	Oral		1.25 Mg, Qd			
		Metformi				S	Oral		500 Mg, Qd			
		Klonopin				S	Oral		0.5 Mg, Bid			
		Prilosec				S	Oral		20 Mg, Bid			
		Carafate				S			1 G, Bid			
		Aggreno	X			S	Oral					
		Flonase				S	Nasal		50 Microgram, Bid			
		Flovent				S	Nasal		110 Microgram, Bid			
			(Albuterol Sulfate)			S	Nasal					
		Imitrex (S	Sumatriptan Succinate)			S	Oral		100 Mg, Prn			



						Dotalioa i	(opert			
	N	litrolingual			S	Sublingual	0.4 Mg, Prn			
	E	pipen			S	Transdermal				
	S	imvastatin			S	Oral				
	Z	yrtec			S	Oral	10 Mg, Qd			
	Lo	ortab			S	Oral				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Oct-2012	8823861	EXPEDITED (15-DAY)			ОТ	US-0095075 1210USA00		55 YR	Female	USA
Preferred Term	<u>P</u>	Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	:
Condition Aggravated:	; Ja	anumet			S		50/500, Qd		Me	erck
Feeling Abnormal; Memory Impairment	С	arafate			S	Oral	1 G, Qd			
Memory impairment	Lo	ozol			S	Oral	1.25 Mg, Qd			
	Z	yrtec			S		10 Mg, Qd			
		Sabapentin			S					
		icodin			S		7.5mg/325mg, Q4h			
		anaflex			S		2 Mg, Bid			
		alsartan			S		160 Mg, Qd			
		upropion Hydrochloride			S		300 Mg, Qd			
		letformin			S		500 Mg, Qd			
		lonopin rilosec			S		0.5 Mg, Bid			
		ggrenox			S S					
	F	lonase			S	Nasal	50 Microgram, Unk			
	F	lovent			S		220 Microgram, Bid			
		entolin (Albuterol)			S					
		nitrex (Sumatriptan)			S		100 Mg, Prn			
		litrolingual			S		0.4 Mg, Prn			
		pipen			S	Transdermal				
		ortab			S	Oral			B 4	anal.
		ocor			S				Me	erck



S Vitamins (Unspecified)

	Flexe	ril			S C						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Oct-2012	8824014	EXPEDITED (15-DAY)			ОТ	US-0095075 1210USA00				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfı</u>	:
Memory Impairment;	Janur	met			S	Oral	Unk			Me	erck
Myocardial Infarction	Zocor	•			S	Oral				Me	erck
	Klono	pin			S	Oral					
	Zyrted	C			S	Oral					
	Gaba	pentin			S	Oral	Unk				
	Vicod	in			S	Oral					
	Zanaf	flex			S	Oral					
	Valsa	rtan			S	Oral					
	Bupro	ppion Hydrochloride			S	Oral					
	Lozol				S	Oral	Pill				
	Prilos	ec			S	Oral					
	Caraf	ate			S	Oral					
	Aggre	enox			S	Oral					
	Flona	se			S	Respiratory (inhalation)	Two S	Sprays Per Nostril			
	Flove	nt			S	Unknown	Two F	Puffs, Bid			
	Vento	olin (Albuterol)			S	Unknown	Two F	Puffs, Q2h			
	Imitre	x (Sumatriptan)			S	Oral					
	Nitroli	ingual			S	Unknown	Spray	/			
	Epipe	en			S	Transdermal					
	Lortal	b			S	Oral					
	Metfo	rmin			S	Oral					

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FDA Received Date	Case #	<u>Case Type</u>	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Oct-2012	882408	80 EXPEDITED (15-DAY	<b>'</b> )		OT	US-009507513 1210USA0007			Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Anxiety; Arterial Disord	der;	Janumet			S		500/50 Mg, Qd		Me	rck
Arthralgia; Asthma; Cardiac Disorder; Che	et	Zanaflex			S	Oral	2 Mg, Bid			
Pain; Depression; Dial	oetic	Gabapentin			S	Oral	2 Df, Tid			
Neuropathy; Fibromya Gastrooesophageal Ro	lgia;	Vicodin			S	Oral	7.5 Mg/325 Mg, Q4h			
Disease; Memory	GIIUX	Valsartan			S	Oral	160 Mg, Qd			
Impairment; Migraine;	ماء	Bupropion Hydrochloride			S	Oral	300 Mg, Qd			
Multiple Allergies; Mus Spasms; Panic Attack	scie	Lozol			S	Oral	1.25 Mg, Qd			
•		Metformin			S	Oral	500 Mg, Qd			
		Klonopin			S	Oral	0.5 Mg, Bid			
		Prilosec			S	Oral	20 Mg, Bid			
		Carafate			S	Oral	1 G, Bid			
		Aggrenox			S	Oral	Unk, Bid			
		Flonase			S	Nasal	4 Df, Qd			
		Flovent			S	Respiratory (inhalation)	2 Df, Bid			
		Ventolin (Albuterol)			S	Respiratory (inhalation)	2 Df, Q2h			
		Imitrex (Sumatriptan)			S	Oral	100 Mg, Prn			
		Nitrolingual			S		1 Df, Prn			
		Epipen			S	Intramuscular				
		Lortab			S	Oral	Unk Df, Unk			
		Zocor			S	Oral	Unk Df, Unk		Me	rck
		Vitamins (Unspecified)			S	Oral	Unk Df, Unk			
		Zyrtec			S	Oral	10 Mg, Qd			



							•				
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	<u>M</u>	fr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Oct-2012	8817399	EXPEDITED (15-DAY)			DE		K-PFIZER INC- 012246113		61 YR	Male	SVK
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>D</u>	osage Text	<u>Duration</u>		<u>Mfr</u>
Death	Epipe	en			S			Unk			Pfizer
	Rytm	onorm			С	Oral		450 Mg, 1 In 1 D			
	Gopte	en "Abbott"			С	Oral		2 Mg, 1 In 1 D			
	Anop	yrin			С	Oral		100 Mg, 1 In 1 D			
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	<u>M</u>	fr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Oct-2012	8828625	EXPEDITED (15-DAY)			ОТ	_	K-PFIZER INC- 012246405		61 YR	Male	SVK
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>D</u>	osage Text	<u>Duration</u>		<u>Mfr</u>
Tachycardia	Epipe	en			S			Unk			Pfizer
	Rytm	onorm			С	Oral		450 Mg, 1 In 1 D			
	Gopte	en "Abbott"			С	Oral		2 Mg, 1 In 1 D			
	Anop	yrin			С	Oral		100 Mg, 1 In 1 D			
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	<u>M</u>	fr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Oct-2012	8837037	EXPEDITED (15-DAY)			ОТ	Cl	HPA2012US02 <sup>-</sup>	1051	61 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>D</u>	osage Text	<u>Duration</u>		<u>Mfr</u>
Anaphylactic Reaction	; Exce	drin Extra Strength		Υ	S	Oral		1-2 Df, Prn			Novartis
Chills; Ear Pain; Headache; Hot Flush; Nasopharyngitis; Oropharyngeal Pain; F Premature Menopause Product Use In Unapproved Indication Sinusitis; Underdose;	e;	en			S			Unk, Unk			



						Dotalloa	topoit				
FDA Received Date 12-Oct-2012	Case # 8671838	Case Type  NON-EXPEDITED	<u>Health</u>		Outcomes OT	Mfr Contr		503B Facility	<u>Age</u>	<u>Sex</u> Male	<u>Country</u> USA
						201216668	3				
Preferred Term	<u>Produc</u>	<u>t</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosage</u>	<u>e Text</u>	<u>Duration</u>	<u>I</u>	<u>//fr</u>
Drug Ineffective	Epipen		S			0.3 Mg, Unk			Pfizer		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
15-Oct-2012	8640393	NON-EXPEDITED				US-PFIZEF 201215054	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>I</u>	<u>Mfr</u>
Cold Sweat; Nausea	Epipen		S			0.3mg, Unk			Pfizer		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Oct-2012	8797305	EXPEDITED (15-DAY)		C	T	US-PFIZEF 201222696	-		66 YR	Female	USA
Preferred Term	eferred Term Product		Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	1	<u>Mfr</u>
Accidental Exposure To Epipen Product; Chest Discomfort; Injection Site Discolouration				S		Unk				Pfizer	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
16-Oct-2012	8801950	EXPEDITED (15-DAY)		C	T	US-PFIZER INC- 2012232285			Male	USA	
			_	0.70	Role	Route	Dosage	e Text	Duration	<u> </u>	<u>Mfr</u>
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Kole		Doouge				
Preferred Term Apnoea	<u>Produc</u> Epipen	<u>t</u>	Comp.	<u>01C</u>	S		Unk				Pfizer
<del>.</del>	Epipen	<u>Case Type</u>				Mfr Contr	Unk	503B Facility	<u>Age</u>		Pfizer <u>Country</u>
Apnoea	Epipen			Prof C	S		Unk ol #		Age		

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Drug Ineffective; Loss Consciousness	Of Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Oct-2012	8822197	NON-EXPEDITED				US-PFIZER 2012240475				Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Injection Site Bruising; Injection Site Haemorrhage	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Oct-2012	8778070	NON-EXPEDITED				US-PFIZER 2012220103	-		2 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	•
Injection Site Pain	Epipen	Jr			S		Unk			Pfi	zer
	Epipen	Jr			S					Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Oct-2012	8769394	EXPEDITED (15-DAY)			ОТ	GB-PFIZER 2012217353	-			Female	GBR
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Contusion; Limb Discomfort	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Oct-2012	8702525	NON-EXPEDITED				US-PFIZER 2012185320			82 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Injection Site Injury; Injection Site Pain; Product Quality Issue	Epipen				S	Intramuscular	0.3 Mg	g, Once In Left Thi	gh	Pfi	zer



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Oct-2012	8780582	NON-EXPEDITED				US-PFIZER 201222111	-		24 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Drug Administration Er Injection Site Pain	ror; Epipen				S	Intramuscular	1 Dos	se As Needed		Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Oct-2012	8829946	EXPEDITED (15-DAY)		0	Г	US-PFIZEF 201224485	-		23 YR	Male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Bone Pain; Drug Administration Error; Myalgia	Epipen				S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Oct-2012	8850451	EXPEDITED (15-DAY)		DI	≣	GB-PFIZEF 201225171	-		11 YR	Male	GBR
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Death; Drug Ineffective	e Epipen				S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	Sex	Country
26-Oct-2012	8392484	NON-EXPEDITED				US-PFIZER 201202778	-			Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Accidental Exposure T Product; Feeling Jittery Injection Site Pain; Inju Associated With Devic Nervousness; Tachyphrenia	/; ıry	Jr			S		0.15	Mg, Unk		Р	fizer

Note: If the field is blank, there is no data.



FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Oct-2012	8838196	NON-EXPEDITED				US-PFIZE 20122518				Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Haemorrhage	Epipen				S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Oct-2012	8851767	NON-EXPEDITED				US-PFIZE 20122577			28 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Dizziness; Hyperventilation	o Epipen				S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Nov-2012	8861314	NON-EXPEDITED				US-PFIZE 20122666			61 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pallor	o Epipen				S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Nov-2012	8873181	EXPEDITED (15-DAY)		C	T	GB-PFIZE 20122664				Female	GBR
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Product; Administered; Heart Ra Increased; Hypertension	uct ate				S		Unk			Pfiz	zer



							<u> </u>			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Nov-2012	8762644	NON-EXPEDITED		(	OT	US-PFIZER IN 2012211442	C-	57 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>-</u>
Drug Ineffective; Produ Quality Issue	uct Epipen				S		0.3 Mg, As Needed		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Nov-2012	8915347	NON-EXPEDITED				US-PFIZER IN 2012282858	C-		Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	[
nsomnia; Mood Altere	d Epipen Benadry	/I			s s		Unk		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Nov-2012	8915473	NON-EXPEDITED				US-PFIZER IN 2012284209	C-	14 YR	Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	
Accidental Exposure T Product; Injection Site Haemorrhage	o Epipen				S		Unk		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Nov-2012	8932551	EXPEDITED (15-DAY)	Υ	ŀ	HO, OT	THQ2012A101	41	61 YR	Female	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>:</u>
Device Failure; Wrong	Lansopi	azole			S		30 Mg (30 Mg, 1-1 D)			
Technique In Product Usage Process	Epipen				S			30 DAY		
-	Etoricox	tib			S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
30-Nov-2012	8928683	EXPEDITED (15-DAY)		1	_T, OT	US-PFIZER IN	∩_	48 YR	Male	USA

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2012292562

Preferred Term	Product	<u> </u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Anaphylactic Shock; Brain Death	o Epipen Benadry	I			s C		Two Epipens Two Doses		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>1#</u> <u>503B Fa</u>	acility Age	<u>Sex</u>	Country
04-Dec-2012	8913091	EXPEDITED (15-DAY)		Н	0	GR-PFIZER 2012244834	INC-		Female	GRC
Preferred Term	Product	1	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Electrocardiogram Abnormal	o Epipen				S		Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>1#</u> <u>503B Fa</u>	acility Age	<u>Sex</u>	Country
06-Dec-2012	8875092	NON-EXPEDITED				US-PFIZER I 2012268062	NC-	46 YR	Male	USA
Preferred Term	Product	1	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective; Produ Quality Issue	uct Epipen				S		0.3 Mg, Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	<u>1#</u> <u>503B Fa</u>	acility Age	<u>Sex</u>	Country
07-Dec-2012	8960564	DIRECT		LT	Γ			48 YR	Male	USA
Preferred Term	Product	1	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Ineffective; Wro	ong Epipen				S				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# <u>503B Fa</u>	acility Age	<u>Sex</u>	Country
10-Dec-2012	8895349	EXPEDITED (15-DAY)		0	Т	US-PFIZER I 2012277566	NC-	8 YR	Male	USA

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<u>Preferred Term</u>		<u>Product</u>	9	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Abdominal Pain Upper		Epipen				S	Unknown	Unk			Р	fizer
Dizziness; Sinusitis; Vi Blurred	ision	Benadryl				С		Unk				
FDA Received Date	Case #	<u>Case Type</u>		<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Dec-2012	896020	64 EXPEDITED (15-I	DAY)			ОТ	US-00950 1212USA0			55 YR	Female	USA
Preferred Term		Product	9	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Arterial Disorder; III-		Simvastatin Tablets, Usp				S	Oral	Unk			N	lerck
Defined Disorder; Mem Impairment	nory	Janumet				S	Oral	50/50	0 Mg, Qd		M	lerck
пправтоп		Prilosec				S	Oral	20 Mg	g, Bid		M	lerck
		Gabapentin				S	Oral	2 Df,	Tid			
		Gabapentin Metformin				S S	Oral	500 N	/lg, Qd			
		Zyrtec				S	Oral	10 Mg	_			
		Vicodin				S	Oral	7.5/3	25 Mg, Q4h			
		Zanaflex				S	Oral	2 Mg	Bid			
		Valsartan				S	Oral	160 N	/lg, Qd			
		Bupropion Hydrochloride				S	Oral	300 N	/lg, Qd			
		Lozol				S	Oral	1.25	Mg, Qd			
		Klonopin				S	Oral	0.5 M	g, Bid			
		Klonopin Carafate				S S	Oral	1 G, I	3id			
		Aggrenox				S	Oral	Unk,	Bid			
		Flonase				S	Nasal	500 N Per N	/lcg, 2 Sprays Daily lostril			
		Flovent				S		110 N Bid	Ig Per Puff, 2 Puffs			
		Ventolin (Albuterol Sulfate)				S	Oral	90 M Q2h	cg Per Puff, 2 Puffs			



						Detailed	rcport				
	Imitre	(Sumatriptan)			S	Oral	100 M	g, Prn			_
	Nitrolii	ngual			S	Oral	0.4 Mg	g, Prn			
	Epipe	n			S	Transdermal	Unk				
	Lortab	1			S	Oral					
	Vitami	ns (Unspecified)			S	Oral	Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Dec-2012	8926702	NON-EXPEDITED				US-PFIZEF 201229106				Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Head Discomfort; Injection S Bruising; Nervousness Pain In Extremity; Paraesthesia; Periphe Swelling; Skin Discolouration; Somnolence	uct Site s;	n			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Dec-2012	8920127	NON-EXPEDITED		0	Т	US-PFIZEF 201228793				Unknown	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Drug Ineffective	Epipe	า			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Dec-2012	8928847	NON-EXPEDITED				US-PFIZEF 201229255			50 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Contusion; Product Quality Issue		n Jr			S		Unk			Pfiz	zer

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Dec-2012	8978035	NON-EXPEDITED		0	т	US-PFIZEF 201231843	-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Swollen Tongue	Epipen				S		Unk			Pfi	zer
	Benadry	/I			S		Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Dec-2012	8990157	EXPEDITED (15-DAY)		D	E	JP-PFIZER 201233031			11 YR	Female	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	•
Drug Ineffective	Epipen				S	Intramuscular	Unk			Pfi	zer
	Epipen				S					Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Dec-2012	8990725	NON-EXPEDITED				US-PFIZEF 201232796				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injury Associa With Device					S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jan-2013	8993464	NON-EXPEDITED				US-PFIZEF 201233095				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jan-2013	8917180	NON-EXPEDITED		0	T	US-PFIZEF 201228658			40 YR	Female	USA

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Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective	Epipen				S		1 Df,	As Needed		Pfi	zer
	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jan-2013	9132260	EXPEDITED (15-DAY)		F	Ю	BE-PFIZ 2013006			5 YR	Unknown	BEL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mfr	
Application Site Pain; Tachycardia	Epipen				S	Cutaneous	1 ln 1	Total		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jan-2013	9011364	NON-EXPEDITED				US-PFIZ 2013004	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site Pain	o Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jan-2013	9005942	NON-EXPEDITED				US-PFIZ 2013007				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mfr	
Insomnia	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jan-2013	9005983	NON-EXPEDITED				US-PFIZ 2012256				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mfr	
No Adverse Event	Epipen				S		Unk			Pfi	zer



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Accidental Exposure To Epipen Jr S 0.15	503B Facility	Age 9 YR	<u>Sex</u> Male	Country USA
Preferred Term Product Comp. OTC Role Route Dosage Accidental Exposure To Epipen Jr S 0.15	age Text	9 YR	Male	1167
Accidental Exposure To Epipen Jr S 0.15	age Text			USA
	90 1021	<u>Duration</u>	<u>Mfr</u>	
Product; Cough; Dyspnoea	5 Mg, As Needed		Pfi	zer
FDA Received Date	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2013 9123829 EXPEDITED (15-DAY) DE, OT US-PFIZER INC- 2013016551			Male	USA
Preferred Term Product Comp. OTC Role Route Dosage	age Text	<u>Duration</u>	<u>Mfr</u>	
Aspiration; Brain Hypoxia; Epipen S Unk Cardiac Arrest; Incorrect Dose Administered; Vomiting	(		Pfi	zer
FDA Received Date	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jan-2013 9123940 NON-EXPEDITED US-PFIZER INC- 2013016549			Male	USA
<u>Preferred Term</u> <u>Product</u> <u>Comp. OTC Role Route</u> <u>Dosage</u>	age Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Epipen S Unk Product; Feeling Jittery	(		Pfi	zer
FDA Received Date	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jan-2013 8773767 NON-EXPEDITED US-PFIZER INC- 2012220213			Female	USA
<u>Preferred Term</u> <u>Product</u> <u>Comp. OTC Role Route</u> <u>Dosage</u>	age Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Bruising Epipen S Unk	(		Pfiz	zer
FDA Received Date	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jan-2013 8947977 NON-EXPEDITED OT US-PFIZER INC- 2012300213			Male	USA

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Preferred Term	Produc	t	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective	Epipen				S		Unk		P	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol # 503B Fa	cility Age	<u>Sex</u>	Country
28-Jan-2013	9033103	EXPEDITED (15-DAY)		Н	0	US-PFI 201303	ZER INC- 0461		Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Chest Pain; Drug	Epipen				S		Unk		Pf	izer
Ineffective; Dyspnoea; Neck Pain; Vomiting	Benadry	/I			S		Unk			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol # 503B Fa	cility Age	<u>Sex</u>	Country
01-Feb-2013	9006433	NON-EXPEDITED				US-PFI 201300	ZER INC- 7251	33 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Blood Pressu Increased; Heart Rate Increased; Injection Si Injury	re				S		Unk		Pi	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol # 503B Fa	<u>cility</u> <u>Age</u>	<u>Sex</u>	Country
05-Feb-2013	9017325	NON-EXPEDITED		0.	Т	US-PFI 201301	ZER INC- 8337		Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Orug Ineffective	Epipen				S		Unk		P	ïzer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol # 503B Fa	cility Age	<u>Sex</u>	Country
05-Feb-2013	9023924	NON-EXPEDITED				US-PFI 201302	ZER INC- 0304		Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Prod					S		0.3 Mg, Prn		Pt	ïzer

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Administered; Hypoaesthesia;

Palpitations; Peripheral

FDA Received Date	Case #	Case Type	<b>Health</b>	Prof (	<u>Outcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
07-Feb-2013	9052358	NON-EXPEDITED				US-PFIZ 2013033	-		4 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Injection Site Haemorrhage; Injection Site Injury; Injection Si Pain	n	n Jr			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2013	8970910	EXPEDITED (15-DAY)		(	TC	GB-PFIZ 2012314	-		30 YR	Unknown	GBR
Preferred Term	Prod	<u>uct</u>	Comp.	<u>otc</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Pain In Extrer Skin Discolouration		n			S	Unknown	Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Cor	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Feb-2013	9097905	NON-EXPEDITED		(	ЭТ	US-PFIZ 2013052	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>otc</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mfr	:
Accidental Exposure T Product; Dizziness	o Epipe	n Jr			S		0.15	Mg		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Feb-2013	9012502	NON-EXPEDITED				US-PFIZ 2013014	-		52 YR	Female	USA

Note: If the field is blank, there is no data.

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Accidental Exposure To Product; Anxiety; Flush Palpitations; Product Quality Issue					s C	Subcutaneous	0.3 Mg Unk	, Single		Pfi	zer
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2013	9082001	NON-EXPEDITED				US-PFIZER I 2013052784	NC-		5 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Contusion; Peripheral Swelling	o Epipen .	Jr			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Feb-2013	9116981	NON-EXPEDITED				US-PFIZER I 2013027980	NC-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mfr</u>	
No Adverse Event	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Feb-2013	9148714	DIRECT			ОТ				54 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Device Malfunction	Epipen				S		One SI	not			
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Mar-2013	9134951	EXPEDITED (15-DAY)			ОТ	US-PFIZER I 2013070894	NC-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Loss Of Consciousness	duct; Loss Of		S	Unk			Pfizer				



							•				
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	<u>  #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Mar-2013	9109809	NON-EXPEDITED			ОТ	US-PFIZER I 2013064943	NC-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	:
Accidental Exposure T Product; Injection Site Injury					S	Unknown	Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2013	9100360	EXPEDITED (15-DAY)			ОТ	GB-PFIZER   2013060288	INC-		2 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Difficult To Use Laceration; Psycholog Trauma		Jr			s C	Intramuscular Oral	1 Df, 1 Unk	I In 1 Total		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Mar-2013	9147811	EXPEDITED (15-DAY)			ОТ	GB-PFIZER   2013077506	INC-		50 YR	Female	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Hypersensitivity	Epipen Salbutar Victoza	mol			s C C	Intramuscular	0.5 Mg Unk Unk	g, Unk		Pfi	izer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Mar-2013	9147240	EXPEDITED (15-DAY)			ОТ	US-PFIZER I 2013076019	NC-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Blood Pressure Increa Heart Rate Increased	sed; Epipen				S		Unk			Pfi	zer



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof 9	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Mar-2013	8998996	NON-EXPEDITED				US-PFIZE 20123309			55 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site					s C		Unk Pro (	'As Needed)		Pfi	zer
Pain; Product Quality Issue					-		1 111 (	As Needed)			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Mar-2013	9159879	EXPEDITED (15-DAY)		(	ОТ	US-PFIZE 20130804	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	Mfr	· -
Haemorrhage; Sedatio	• • • • • • • • • • • • • • • • • • • •				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Mar-2013	9154302	NON-EXPEDITED				US-PFIZE 20130804	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	Mfr	
Contusion	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Mar-2013	9159724	NON-EXPEDITED				US-PFIZE 20130804	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mfr	
Euphoric Mood	Epipen				S		Unk			Pfi	zer
	Benadry	yl			S		2 Sh	ots			
	Zantac				S		Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2013	9213121	NON-EXPEDITED				US-PFIZER INC- Female US 2013102995				USA	

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Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>Text</u>	<b>Duration</b>	<u>M</u> 1	<u>fr</u>
Accidental Exposure T Product; Heart Rate Increased	o Epipe	n			S		0.3 Mg,	Unk		Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Apr-2013	9216640	NON-EXPEDITED		Н	O, OT	US-PFI 201310	ZER INC- 5378			Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Anaphylactic Reaction	Epipe	n			S		Unk			Р	fizer
	Benad	dryl			S		Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Apr-2013	9217573	NON-EXPEDITED				US-PFI 201309	ZER INC- 8889		60 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Injection Site Pain; Inju Associated With Devic		n			S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Apr-2013	9174007	NON-EXPEDITED				US-PFI 201308	ZER INC- 8596			Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Hypoaesthesia	Epipe	n			S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Apr-2013	9196407	NON-EXPEDITED				US-PFIZER INC- 2013095787				Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Drug Ineffective; Pain	Epipe	n			S		Unk			Р	fizer

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2013	9242436	NON-EXPEDITED				US-PFIZ 2013120	ZER INC- 0823			Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Injection Site Pain	Epipe	n			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof O	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Apr-2013	9229017	NON-EXPEDITED				US-PFIZ 2013108	ZER INC- 3185		75 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pallor		n			S		0.3 M	I, As Needed		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2013	9175793	NON-EXPEDITED				US-PFIZ 2013087	ZER INC- Z297			Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Incorrect Route Of Dru Administration; Tremo		n			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2013	9181276	NON-EXPEDITED				US-PFIZ 2013088	ZER INC- 8890			Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Pain In Extremity	Epipe	n			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof O	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2013	9210535	NON-EXPEDITED				US-PFIZ 2013103	ZER INC- 3258		12 YR	Female	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosag	e Text	Duration	Mfr	

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Unk

Accidental Exposure To Product: Injection Site

S Epipen

Pfizer

Haemorrhage; Injection Site Site Pain	n										
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-May-2013	9176756	EXPEDITED (15-DAY)			DE		US-PFIZER INC- 2013088875		19 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dos</u>	age Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen				S		Un	k		Pfiz	er
	Epipen				S					Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-May-2013	9213061	NON-EXPEDITED					US-PFIZER INC- 2013104339			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dos</u>	age Text	<b>Duration</b>	<u>Mfr</u>	
Feeling Jittery	Epipen				S		Un	k		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-May-2013	9219393	NON-EXPEDITED					US-PFIZER INC- 2013105360			Unknown	USA
<u>Preferred Term</u>	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dos</u>	age Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Energy Increa					S		Un	k		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-May-2013	9271878	NON-EXPEDITED					US-PFIZER INC- 2013069222			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dos</u>	age Text	<u>Duration</u>	Mfr	
No Adverse Event	Epipen				S		Un	L.		Pfiz	er

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country		
10-May-2013	9284362	EXPEDITED (15-DAY)		C	T	US-PFIZEF 201314657			47 YR	Male	USA		
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>		
Accidental Exposure T Product; Injection Site Discolouration; Injectio Site Pain; Injection Site Pallor; Paraesthesia O Vasoconstriction	Diphenl on e	nydramine			S C		50 Mg	, Single		Р	fizer		
FDA Received Date	Case #	Case Type	Health	Prof C	<u>utcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>		
15-May-2013	9223283	EXPEDITED (15-DAY)		D	E, OT	US-PFIZEF 201311157			8 YR	Male	USA		
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>M</u> 1	<u>ir</u>		
Cardiac Arrest; Drug Ineffective; Hypersensitivity; Respiratory Arrest	Epipen				S		Unk			Р	fizer		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>		
15-May-2013	9239130	EXPEDITED (15-DAY)		С	T	US-PFIZEF 201311729			54 YR	Female	USA		
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>		
Blood Pressure Fluctuation; Dysstasia Hypersomnia; Weight Decreased	Epipen ;				S		0.3 Mg	g, As Needed		Р	fizer		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>		
16-May-2013	9257529	NON-EXPEDITED		C	T	US-PFIZER INC- 2013126800				Female	USA		
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>		
Drug Ineffective	Epipen			S			Unk			Pfizer			

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2013	9257484	NON-EXPEDITED				US-PFIZ 2013126	ER INC- 814			Male	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Injection Site Pain	Epipen				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2013	9266745	EXPEDITED (15-DAY)			ОТ	CA-PFIZ 2013131	ER INC- 415			Unknown	CAN
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
njection Site Injury; Product Quality Issue	Epipen				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2013	9269542	EXPEDITED (15-DAY)			DE, HO, OT	US-PFIZ 2013134	ER INC- 512		11 YR	Male	USA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Cardiac Arrest; Drug	Epipen				S		Unk			Pf	izer
neffective	Epipen				S					Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
24-May-2013	9307810	EXPEDITED (15-DAY)			НО	GB-PFIZ 2013157	ZER INC- '133			Male	GBR
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Heart Rate Irregular; Tachycardia	Epipen				S	Unknown	1 Dos Total	age Forms,1 In 1		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2013	9210932	EXPEDITED (15-DAY)			ОТ	GB-PFI2 2013091	ZER INC- 324		53 YR	Male	GBR

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Epipen

#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unk

Injection Site Bruising;

Injection Site

Haemorrhage; Injection Site Pain; Product Quality

Issue FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Sex Country <u>Age</u> 29-May-2013 9314482 NON-EXPEDITED OT **US-PFIZER INC-**Unknown USA 2013158231 **Preferred Term Product OTC** Role **Route Dosage Text** Mfr Comp. Duration S Drug Effect Incomplete: **Epipen** Pfizer Unk **Expired Product** S Epipen Pfizer Unk Administered С Albuterol Unk FDA Received Date Case # Case Type **Health Prof Outcomes** Mfr Control # 503B Facility Sex <u>Age</u> Country **US-PFIZER INC-**USA 04-Jun-2013 9316592 NON-EXPEDITED 35 YR Female 2013137012 **Preferred Term** Mfr **Product** Comp. OTC Role Route **Dosage Text** Duration No Adverse Event Epipen S Pfizer Intramuscular 0.3 Mg, Prn С Cetirizine Oral 10 Mg, Qid С Metformin Oral 500 Mg, 2x/Day С Prilosec Oral 40 Mg, 1x/Day С Warfarin Oral 5 Mg, 1x/Day Ativan С Oral 1 Mg, Qhs С Singulair Oral 10 Mg, Qhs С Prozac Oral 40 Mg, 1x/Day С Doxepin Oral 25 Mg, Qhs С Oxycodone Oral 10 Mg, Q4h Prn С Pro-Air 2 Puffs, Q4h С Hydroxychloroquine Oral 200 Mg, 2x/Day

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Pfizer



FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Cont	rol#	503B Facility	Age	Sex	Country
05-Jun-2013	9290302	NON-EXPEDITED				US-PFIZEI 201314504	R INC-		52 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	Mfr	:
Accidental Exposure T Product; Injection Site Haemorrhage; Pain In Extremity		n			S	Intramuscular	1:10	000, 0.3 MI, Prn		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2013	9291971	NON-EXPEDITED		(	OT	US-PFIZEF 201314665	-			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	Mfr	
Drug Ineffective	g Ineffective Epipen				S		Unk			Pfi	zer
Epipen Epipen Benadryl		n			S S S		Unk				zer zer
	Benad Benad	•			S S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2013	9295071	NON-EXPEDITED				US-PFIZEI 201314787				Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Contusion; Pain	Epipe	n			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u> Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2013	9341294	DIRECT	Υ	(	ОТ				60 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Injection Site Haemorrhage; Injection Site Pain; Ne	• •	n			S	Intramuscular				Му	/lan

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Issue											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
11-Jun-2013	9294760	NON-EXPEDITED				US-PFIZE 20131478				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Contusion; Skin Burnir Sensation	ng Epipen				S		Unk			P	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2013	9296881	EXPEDITED (15-DAY)		(	DΤ	US-PFIZE 20131495				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Drug Administration El Injection Site Injury	rror; Epipen				S		Unk			P	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jun-2013	9302989	EXPEDITED (15-DAY)		(	OT	GB-PFIZE 20131542	-			Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>M</u> f	<u>ir</u>
Seizure	Epipen				S		Unk			P	fizer
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2013	9315698	EXPEDITED (15-DAY)				GB-PFIZE 20131643			40 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Heart Rate Increased; Hyperhidro Injection Site Bruising; Injection Site Paraesthesia; Injectior Site Swelling; Respirat Rate Increased	sis;				S		Unk			P	fizer



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jun-2013	9330234	EXPEDITED (15-DAY)		0	T	US-PFIZE 20131681			9 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Cardiac Disorder	Epipen				S	Subcutaneous	Unk			Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2013	9359245	NON-EXPEDITED		0	T	US-PFIZE 20131807			50 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Drug Ineffective	Epipen				S	Intramuscular	0.3 Mg	g, As Needed		Р	fizer
	Albutero	ol Solution For Nebulizer			С	Oral	Unk				
	Provent	il Mdi			С	Oral	Unk, A	As Needed			
	Advair				С	Oral	Unk				
	Spirono	lactone			С	Oral	25 Mg	, 1x/Day			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2013	9336618	NON-EXPEDITED				US-PFIZE 20131709			40 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product; Injection Site Bruising; Injection Site Pallor; Limb Discomfor		Jr			S		1:2000 Injectio	0, 0.3 MI, 1 Time (1 on)		P	fizer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2013	9349268	EXPEDITED (15-DAY)		D	E	US-PFIZE 20131750	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Drug Ineffective	Epipen				S		Unk			Р	fizer



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	•		503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2013	9349529	NON-EXPEDITED				US-PFIZI 20131750				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Fatigue	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2013	9395154	EXPEDITED (15-DAY)		0	Г	CA-PFIZI 2013199				Male	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage	Epipen				S	Intramuscular				Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2013	9343164	EXPEDITED (15-DAY)		0	Γ	US-PFIZI 20131720			23 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Hypoaesthes Pallor; Paraesthesia					S		1:1000	), 0.3 MI		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2013	9351273	EXPEDITED (15-DAY)		0	Г	US-PFIZI 20131778				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Administration Er Gait Disturbance; Pain Peripheral Swelling			S			Unk			Pfi	zer	
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2013	9365043	NON-EXPEDITED		0	Γ	US-PFIZER INC- 2013184839			52 YR	Female	USA
			Comp.	отс	Role		Dosage			Mfr	

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# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective	Epipen				S			0.3 MI, As Needed T Daily	wice	Pfiz	zer
	Armour	Thyroid			С	Oral		30 Mg, 1x/Day			
	Potassiu	um Chloride			С	Oral		20 Meq, 2x/Day			
	Hydroch	nlorothiazide/Triamterene			С	Oral		37.5/25 Mg, Daily			
	Clonaze	epam			С	Oral		0.5 Mg, (1/2 To 1 Ta Daily) As Needed	blet		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes		Mfr Control #	503B Facilit	y <u>Age</u>	<u>Sex</u>	Country
15-Jul-2013	9353880	NON-EXPEDITED			ОТ		US-PFIZER INC 2013178189	;-	57 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Rout	<u>te</u>	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Arthralgia;	Epipen				S	Subci	utaneous	0.3 Mg, As Needed		Pfiz	zer
Musculoskeletal Discomfort; Seizure	Benadry	<b>/</b> I			S			Unk			
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof	Outcomes		Mfr Control #	503B Facilit	<u>y Age</u>	<u>Sex</u>	Country
15-Jul-2013	9355732	NON-EXPEDITED					US-PFIZER INC 2013179544	;-		Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Rout	<u>te</u>	Dosage Text	<b>Duration</b>	Mfr	
Pain	Epipen				S			Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #	503B Facilit	y <u>Age</u>	<u>Sex</u>	Country
15-Jul-2013	9363075	NON-EXPEDITED					US-PFIZER INC 2013183514	;-		Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Rout	<u>te</u>	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pain	o Epipen				S			Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #	503B Facilit	y <u>Age</u>	<u>Sex</u>	Country
16-Jul-2013	9356266	NON-EXPEDITED					US-PFIZER INC 2013179550	:-	87 YR	Male	USA

Note: If the field is blank, there is no data.



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Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>fr</u>
Drug Ineffective; Expire		Epipen			S	Intramuscular	0.30 Mg, As Needed		Р	fizer
Product Administered; Product Quality Issue		Hydrochlorothiazide			С	Oral	25 Mg, 1x/Day			
		Sertraline			С	Oral	100 Mg, 1x/Day			
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2013	935797	3 NON-EXPEDITED				US-PFIZI 2013179		73 YR	Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>M</u> 1	<u>fr</u>
Accidental Exposure T	ō	Epipen			S		1:1000, 0.3 MI, 1 Time	e	Р	fizer
Product; Injection Site Coldness; Injection Sit	e	Actonel			С	Oral	150 Mg, Monthly			
Pain		Metformin			С	Oral	500 Mg, 2tabs Bid			
		Lisinopril W/Hydrochlorothiazide	)		С	Oral	20/12.5 Mg			
		Simvastatin			С	Oral	40 Mg Daily			
		Finasteride			С	Oral	5 Mg Daily			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Con	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2013	936614	9 EXPEDITED (15-DAY	)	C	DΤ	US-PFIZI 20131850	=		Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M1</u>	<u>fr</u>
Loss Of Consciousnes	ss	Epipen			S		Unk		Р	fizer
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2013	936953	0 NON-EXPEDITED		C	T	US-PFIZI 2013188			Male	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M1</u>	<u>fr</u>
Drug Ineffective		Epipen			S		Unk		Р	fizer
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2013	937580	4 NON-EXPEDITED				US-PFIZI	ER INC-	35 YR	Male	USA

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Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Asthenia; Migraine; Nausea; Tre					S	Intramuscular	0.3 Mg, As Needed		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2013	9321014	NON-EXPEDITED				US-PFIZER   2013164252	NC-	38 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Contusion	Epipen				S		Unk		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2013	9397049	NON-EXPEDITED				US-PFIZER I 2013202402	NC-		Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Injection Site Pain	Epipen				S		Unk		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jul-2013	9390944	NON-EXPEDITED		0	Т	US-PFIZER   2013198195	NC-	47 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Drug Ineffective	Epipen				S	Intramuscular	0.3 Mg, As Needed, 1:1000, 0.3 Ml		Pfiz	er
	Epipen				S		0.3 Mg, As Needed		Pfiz	er
	Benadr	yl			С	Oral	50 Mg, 2 Tablets Every 4 Hrs			
	Vitamir				С	Oral	100 Mg, 1x/Day			
	Omepr	azole			С	Oral	20 Mg, 1x/Day			



	Lisinop	oril			С	Oral	10 Mg	, 1x/Day			
	Vitamir	ns			С	Oral	Unk, C	Qd			
	Acetyls	salicylic Acid			С	Oral	81 Mg	, 1x/Day			
	Lactulo	ose			С	Oral	10 Gm	n/15 MI, Bid			
	Colesty	yramine			С	Oral	Unk				
	Ibuprof	en			С	Unknown	Unk, P	rn			
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jul-2013	9394630	NON-EXPEDITED				US-PFIZE 201320147				Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Accidental Exposure T Product By Child	o Epipen	1			S	Unknown	0.3 Mg	յ, Unk		Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
22-Jul-2013	9418947	DIRECT	Υ						11 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
ncorrect Drug Administration Duratio Vrong Technique In Product Usage Proces	·				S	Intramuscular					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2013	9422575	DIRECT	Υ						49 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Circumstance Or nformation Capable C Leading To Medication Error; Drug Administra Error	า				S	Cutaneous				D	Pey



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

25268  Product  Epipen Jr	Case Type  EXPEDITED (15-DAY)  Case Type  DIRECT	Comp.		Outcomes OT Role S	Mfr Contr GB-PFIZEF 201321961 Route	R INC-	503B Facility e Text	Age 3 YR  Duration	Sex Male	<u>Country</u> GBR
Product Epipen Jr se # 26446	Case Type			Role	201321961	4	<u>e Text</u>			GBR
Epipen Jr se # 26446	Case Type		OTC		Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
<b>se #</b> 26446	Case Type	<u>Health</u>		S						
26446		<u>Health</u>				Unk			Pfiz	er
	DIRECT		Prof (	<u>Outcomes</u>	Mfr Conti	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Product			L	LT				65 YR	Male	USA
<u>i ioudot</u>		Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epipen				S					Myl	an
se #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Conti	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
92932	NON-EXPEDITED				US-PFIZEF 201319821			36 YR	Female	USA
Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epipen Jr ;				S		1:200	0, 0.3 Ml, Single		Pfiz	er
se #	Case Type	Health	Prof (	<u> Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05572	NON-EXPEDITED					-			Female	USA
Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	Mfr	
Epipen				S		Unk			Pfiz	er
se #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Conti	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
<del></del>	NON EVDEDITED		(	ΩT.	US-PFIZEF			16 YR		
s 0	Epipen Jr  e #  5572  Product  Epipen  e #	Epipen Jr  E # Case Type  5572 NON-EXPEDITED  Product Epipen  E # Case Type	Epipen Jr  e # Case Type Health  5572 NON-EXPEDITED  Product Comp.  Epipen	Epipen Jr  e # Case Type Health Prof ( 5572 NON-EXPEDITED  Product Comp. OTC  Epipen  e # Case Type Health Prof (	Epipen Jr S  e # Case Type Health Prof Outcomes  5572 NON-EXPEDITED  Product Comp. OTC Role Epipen S  e # Case Type Health Prof Outcomes	Product Comp. OTC Role Route  Epipen Jr S  E # Case Type Health Prof Outcomes US-PFIZER 201320607  Product Comp. OTC Role Route  Epipen S  E # Case Type Health Prof Outcomes Mfr Contr	Product Comp. OTC Role Route Dosage Epipen Jr S 1:200  e # Case Type Health Prof Outcomes US-PFIZER INC- 2013206079  Product Comp. OTC Role Route Dosage Epipen S Unk  e # Case Type Health Prof Outcomes Mfr Control #	Product Epipen Jr  Comp. OTC Role Route  S 1:2000, 0.3 MI, Single  ## Case Type Health Prof Outcomes US-PFIZER INC-2013206079  Product Epipen  Comp. OTC Role Route Dosage Text US-PFIZER INC-2013206079  Product Epipen S Unk  ## Case Type Health Prof Outcomes Mfr Control # 503B Facility US-PFIZER INC-2013206079  **Dosage Text**  **Dosage Text** **Dosage Text** **Dosage Text** **Dosage Text** **Epipen** **	Product Comp. OTC Role Route Dosage Text Duration  Epipen Jr S 1:2000, 0.3 MI, Single  e # Case Type Health Prof Outcomes US-PFIZER INC-2013206079  Product Comp. OTC Role Route Dosage Text Duration  Epipen S Unk  Case Type Health Prof Outcomes Mfr Control # 503B Facility Age	Product Comp. OTC Role Route Dosage Text Duration Mfr  Epipen Jr S 1:2000, 0.3 MI, Single Pfiz  E # Case Type Health Prof Outcomes US-PFIZER INC- 2013206079  Product Comp. OTC Role Route Dosage Text Duration Mfr  Epipen S Unk Pfiz

Note: If the field is blank, there is no data.



#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

						Dotanoa	Noport				
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Drug Effect Delayed	Epipen				S	Intramuscular	0.6 Mg	, As Needed		Р	fizer
	Buspar				С	Oral	Unk				
	Zoloft				С	Oral	Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2013	9418733	NON-EXPEDITED				US-PFIZE 201321310			5 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M1</u>	<u>ir</u>
Accidental Exposure T Product By Child; Expi Product Administered; Nervousness					S		Unk			P	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2013	9415444	NON-EXPEDITED				US-PFIZE 201321057				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Accidental Exposure T Product; Psychomotor Hyperactivity	o Epipen				S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2013	9423404	NON-EXPEDITED		0	Γ	US-PFIZE 201321572	-		30 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Drug Ineffective; Produ Quality Issue	uct Epipen				S	Intramuscular	0.3 Mg Doses	, As Needed, Two		P	fizer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Aug-2013	9440648	NON-EXPEDITED				US-PFIZE 201322242				Female	USA

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							•				
Injection Site Haemorrhage; Injury Associated With Devic Peripheral Swelling	Epipen ee;				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Aug-2013	9450825	NON-EXPEDITED				US-PFIZEI 201320884			62 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Effect Incomplete	e Epipen				S	Intramuscular	0.3 Mg,	As Needed		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Aug-2013	9439655	NON-EXPEDITED			ОТ	US-PFIZEI 201322272				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen Epipen				s s		Unk			Pfi: Pfi:	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Aug-2013	9439703	NON-EXPEDITED				US-PFIZEI 201322250				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pain		Jr			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Aug-2013	9397550	EXPEDITED (15-DAY)			ОТ	US-PFIZEI 201320148			39 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Product; Administered; Hyperhidrosis; Injection	uct				S		Unk			Pfi	zer



Site Bruising; Injection Site Hypoaesthesia; Injection Site Pain: Vomiting

Site Pairi, voiriiting											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	# <u>503B</u>	<u>Facility</u>	<u>Age</u>	<u>Sex</u>	Country
16-Aug-2013	9461244	NON-EXPEDITED				US-PFIZER IN 2013235457	IC-		83 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text		<u>Duration</u>	<u>Mfr</u>	
Flushing; Pain	Epipen				S	Intramuscular	0.30 Mg, Unk			Pfi	zer
	Fish Oil				С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control	# <u>503B</u>	Facility	<u>Age</u>	<u>Sex</u>	Country
20-Aug-2013	9466984	NON-EXPEDITED				US-PFIZER IN 2013237747	IC-		21 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>		<u>Duration</u>	<u>Mfr</u>	
Expired Product	Epipen				S	Intramuscular	0.3 Mg, As Ne	eded		Pfi	zer
Administered; Injection Site Pain	Albutero	ol			С	Respiratory (inhalation)	Prn, Unk				
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Outcomes</u>	Mfr Control	# <u>503B</u>	<u>Facility</u>	<u>Age</u>	<u>Sex</u>	Country
21-Aug-2013	9447468	NON-EXPEDITED				US-PFIZER IN 2013226418	IC-		30 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>		<u>Duration</u>	<u>Mfr</u>	
Tremor	Epipen				S	Intramuscular	0.3 Mg, As Ne	eded		Pfi	zer
	Epipen				S					Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	<u>#</u> 503B	Facility	<u>Age</u>	<u>Sex</u>	Country
21-Aug-2013	9472230	DIRECT								Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text		<u>Duration</u>	<u>Mfr</u>	
Circumstance Or Information Capable O	Epipen of				S						

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Leading To Medication

Error: Medication Error

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
22-Aug-2013	9422619	NON-EXPEDITED				US-PFIZER 201321578			60 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Expire	ed Epipe	en			S	Intramuscular	0.3 Mg	g, As Needed			Pfizer
Product Administered; Insomnia; Restless Leg Syndrome; Somnolence					S S	Unknown	Unk				Pfizer
Syndrome, Sommoleno	Tram	adol			С	Unknown	Unk				
	Valiu	m			С	Unknown	Unk				
	Prava	astatin			С	Unknown	Unk				
	Glybu	uride			С	Unknown	Unk				
	Stratt	era			С	Unknown	Unk				
	Vesic	care			С	Unknown	Unk				
	Pulm	icort			С	Unknown	Unk				
	Zolpi	dem Tartrate			С	Unknown	Unk				
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Aug-2013	9443523	NON-EXPEDITED				US-PFIZER 201322370			58 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Injection Site Pain;	Epipe	en			S		0.3 Mg	g Prn			Pfizer
Product Quality Issue	Bena	dryl			С		Unk, F	Prn			
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	Sex	Country
22-Aug-2013	9449631	NON-EXPEDITED		(	T	US-PFIZER 201322787				Unknov	vn USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective	Epipe	en			S		Unk				Pfizer

Date - Time: 15-May-2018 01:32:07 PM EST

Note: If the field is blank, there is no data.

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
22-Aug-2013	9471046	NON-EXPEDITED			ОТ	US-PFIZE 20132398			53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Drug Ineffective	Epipe	en			S		0.3 Mg,	Single			Pfizer
	Bena	dryl			С	Oral	Unk	-			
	Albut	erol			С	Oral	Prn				
	Effex	or-Xr			С	Oral	300 Mg / Noon	Am, 75 Mg At			
	Topa	max			С	Oral	50 Mg A	m, 150 Mg Hs			
	Lantu	IS			С	Subcutaneous	30 Units	Am, 30 Units Pm			
	Nexiu	ım			С	Oral	Qam				
	Ativa	n			С	Oral	4mg, Un	k			
	Singu	ılair			С	Oral	Hs				
	Trazo	odone			С	Oral	100 Mg,	Hs			
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Aug-2013	9471061	EXPEDITED (15-DAY)			ОТ	GB-PFIZE 20132437			2 YR	Male	GBR
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Device Failure; Pain; Procedural Complicati Wound	Epipe on;	en			S	Intramuscular	0.15 Mg	, As Needed			Pfizer
FDA Received Date	Case #	Case Type	<b>Health</b>	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Aug-2013	8874815	NON-EXPEDITED				US-PFIZE 20122593			73 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Arthralgia; Back Pain; Blood Pressure Increa Headache; Product		en			S		Unk				Pfizer

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#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quality Issue; Tendonitis;

I rio	ner	Finger

Trigger Finger											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Aug-2013	9474789	NON-EXPEDITED		0.	Γ	US-PFIZ 2013245	-		53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipe	en			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Aug-2013	9461272	NON-EXPEDITED				US-PFIZ 2013234	-			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Tremor	o Epipe	en			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Aug-2013	9475804	NON-EXPEDITED				US-PFIZ 2013242				Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective; Expir Product Administered	ed Epipe	en			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Aug-2013	9458049	NON-EXPEDITED				US-PFIZ 2013231				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Expired Prod Administered; Injection Site Hypoaesthesia	uct	en			S	Unknown	0.3 M	lg, Unk		Pfi.	zer



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

							•				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Aug-2013	9479380	NON-EXPEDITED				US-PFIZER I 2013244993	NC-		51 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered; Injectior Site Injury; Pain In Extremity; Product Qu ssue	uct 1				S		0.3 M	g, Unk		Pf	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Aug-2013	9460126	EXPEDITED (15-DAY)		0	Т	US-PFIZER I 2013232536	NC-		32 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered; Injectior Site Haemorrhage; njection Site Hypoaesthesia; Periph Coldness; Skin Discolouration	uct				S		0.3 M	I, As Needed		Pf	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Aug-2013	9486242	NON-EXPEDITED		0.	Т	US-PFIZER I 2013247004	NC-		19 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mf	<u>r</u>
Swallon Tangua, Hitia	aria Epipen				S	Intramuscular	0.3 M	g, As Needed		Pf	fizer
Swollen Tongue; Urtic	<u> </u>										
FDA Received Date		Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
		Case Type NON-EXPEDITED	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro US-PFIZER I 2013246847		503B Facility	Age 58 YR	<u>Sex</u> Female	Country USA



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective	Epiper	1			S	Intramuscular	0.3 Mg, As Needed			Pfizer
	Zolpid	em			С	Oral	10 Mg, As Needed			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Aug-2013	9491936	NON-EXPEDITED		ŀ	НО	US-PFIZER IN 2013246858	C-	63 YR	Male	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Drug Ineffective	Epiper	1			S	Unknown	0.3 Mg, As Needed			Pfizer
	Metfor	min			С	Oral	500 Mg, Unk			
	Lisino	oril			С	Oral	Unk			
	Gabap	entin			С	Oral	Hs			
	Trazoo	done			С	Oral	Hs			
	Benad	ryl			С		25 Mgx1 Approx <1 Min			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Sep-2013	9494523	EXPEDITED (15-DAY)		[	DE, OT	US-PFIZER IN 2013251022	C-	8 YR	Male	USA
Preferred Term	Produ	ct	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	ļ	<u>Mfr</u>
Cardiac Arrest; Cyano: Hypotension	sis; Epiper	n			S	Intravenous (not otherwise specified)	Unk			Pfizer
	Dipher	nhydramine			С		Unk			
	Albute				C C		110 Mcg 2 Puffs Two			
	Flover	ıı					Times A Day			
	Flover Zyrtec				С					
					C C		Times A Day			
FDA Received Date	Zyrtec		Health	Prof (		Mfr Control #	Times A Day 5 Mg, As Needed 2 Puffs As Needed	Age	<u>Sex</u>	Country
FDA Received Date 04-Sep-2013	Zyrtec Albute	rol			С	Mfr Control at US-PFIZER IN 2013221268	Times A Day 5 Mg, As Needed 2 Puffs As Needed  503B Facility	<b>Age</b> 13 YR	<u>Sex</u> Female	<u>Country</u> USA



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Hypersensitivity; Laryngeal Oedema	sitivity; I Oedema				S		3 Df (Epipens), Unk	Pfiz		izer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Sep-2013	9450455	NON-EXPEDITED				US-PFIZER 2013227842		33 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>.</u>
Accidental Exposure T	o Epipe	en			S		0.3 Mg, As Needed		Pf	izer
Product; Energy Increased; Therapeutic Response Unexpected		erol			С	Respiratory (inhalation)	Unk			
теоропос опехреске	Proto	nix			С	Oral	Unk			
	Hydro	ochlorothiazide			С	Oral	Unk			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Sep-2013	9503159	NON-EXPEDITED			ОТ	US-PFIZER 2013253388			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mf	
Drug Ineffective	Epipe	en			S		0.3 Mg, Prn		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Sep-2013	9503186	NON-EXPEDITED			ОТ	US-PFIZER 2013252080		73 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	
Drug Ineffective; Produ	uct Epipe	en			S	Intramuscular	0.3 Mg, 1x/Day		Pf	izer
Quality Issue	Verap	oamil			С	Oral	240 Mg, 1x/Day			
	Simva	astatin			С	Oral	20 Mg, 1x/Day			
	Losar	tan			С	Oral	50 Mg, 1x/Day			
	Lyrica	a			С	Oral	150 Mg, 2x/Day			
	Advai	ir			С	Oral	500/50 Mg (1000/100mg In Morning And Evening	)		



### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

						Detailed	report				
	Paroxet				С	Oral	Unk				
	Albutero	ol .			С	Oral	Prn				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
06-Sep-2013	9503332	EXPEDITED (15-DAY)			ОТ	US-PFIZEF 201325337	-		38 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T	o Epipen				S	Intramuscular	0.3 Mg	a		Pfi	zer
Product; Injection Site Discolouration; Injection Site Pain		olol			С	Oral		ι, 1x/Day			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Sep-2013	9520461	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2013S1019			28 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Injectior Site Pallor	uct	Jr			S	Intramuscular				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2013	9537061	NON-EXPEDITED				US-PFIZEF 201327000	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Blood Pressure Abnor Erythema; Headache; Peripheral Swelling;	mal; Epipen				S		Unk			Pfi	zer
Swelling Face				D (	0	Mfr Contr	ol #	503B Facility	Age	<u>Sex</u>	Country
Swelling Face	Case #	Case Type	<u>Health</u>	Prot	<u>Outcomes</u>	<u>IVIII COITLI</u>	<u> </u>	occo i domity	<u>- 190</u>	<u> </u>	
	<b>Case #</b> 9546566	Case Type EXPEDITED (15-DAY)	<u>Health</u>		OT	US-MYLAN 2013S1021	ILABS-	<u> </u>		Female	USA



Drug Effect Decreased Dyspnoea; Expired Product Administered	d; Epipe	n			S					Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2013	9557975	EXPEDITED (15-DAY)		Н	O, OT	GB-MYLA 2013S10				Female	GBR
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n			S					Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Sep-2013	9565302	EXPEDITED (15-DAY)		0	Т	US-MYLA 2013S10			54 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	Mfr	:
Device Failure; Drug D Omission	Dose Epipe Benad	n 2-Pak dryl			S C	Intramuscular				Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Sep-2013	9565593	EXPEDITED (15-DAY)		0	Т	US-MYLA 2013S10			9 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	Mfr	
Device Failure; Injection Site Bruising	on Epipe	n 2-Pak			S	Intramuscular				Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Oct-2013	9601240	EXPEDITED (15-DAY)		Lī	Г, ОТ	AU-MYLA 2013S10			64 YR	Female	AUS
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Device Deployment Is: Drug Ineffective; Inject Site Bruising; Injection Discolouration; Pain In Extremity	tion Site	n			S	Intramuscular				Му	⁄lan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Con	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2013	9618969	EXPEDITED (15-DAY)		C	T	FI-MYLAN 2013S102			5 YR	Female	FIN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mf	<u>r</u>
Device Failure	Epipen				S	Intramuscular				M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Oct-2013	9628867	EXPEDITED (15-DAY)		H	Ю	BE-MYLA 2013S102			54 YR	Female	BEL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mf	<u>r</u>
Drug Ineffective; Paraesthesia; Wrong	Epipen				S	Intramuscular					ylan
Technique In Product Usage Process	Adrenal	ine			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2013	9639113	EXPEDITED (15-DAY)		C	T	US-MYLA 2013S102			41 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mf	<u>r</u>
Device Failure; Drug D Omission	Oose Epipen				S	Intramuscular				M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Oct-2013	9640701	DIRECT		C	T				67 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	<u>r</u>
Amnesia; Anaphylactic Shock; Angina Pectori Muscle Spasms					S		1 Dos	se			
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2013	9548221	EXPEDITED (15-DAY)		C	T	US-MYLA 2013S102			33 YR	Female	USA



Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen 2	2-Pak			S	Intramuscular			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Oct-2013	9659661	EXPEDITED (15-DAY)		D	E	US-MYLAN 2013S1024		58 YR	Male	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Drug Effect Decreased	I Epipen				S				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Nov-2013	9667981	NON-EXPEDITED		D	E	US-PFIZER 201331245	=	58 YR	Male	USA
Preferred Term	Product	<u>I</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Effect Decreased	ug Effect Decreased Epipen				S		0.3 Mg, Unk		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Nov-2013	9671112	NON-EXPEDITED				US-PFIZER 201331389			Male	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hot Flush; Hypersensitivity	Epipen				S	Intramuscular	0.3 Mg, As Needed		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Nov-2013	9677455	DIRECT		D	S, HO, LT	ОТ		1 YR	Female	USA
Preferred Term	Product	Ŀ	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Disturbance In Attentio Skin Discolouration; Unresponsive To Stimu	•				S		2 Shots, Into The Muscle	e	Му	lan

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Nov-2013	9686664	EXPEDITED (15-DAY)		(	OT	US-MYI 2013S1	ANLABS- 025239			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Seizure	Epipen	Jr 2-Pak			S	Intramuscular				М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Nov-2013	9563922	EXPEDITED (15-DAY)		[	DE	CA-JNJ 201309			13 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Drug Ineffective;		/I Unspecified		Υ	S	Oral					
Dyspnoea; Pharyngea Oedema; Vomiting	l Epipen				S	Unknown					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Nov-2013	9691318	EXPEDITED (15-DAY)		l	_T	CA-MYI 2013S1	ANLABS- 025342		58 YR	Male	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	g <u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure	Epipen Crestor				S C					М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Nov-2013	9703915	NON-EXPEDITED				US-PFI 201333	ZER INC- 1315		38 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Drug Hypersensitivity	Aldacto	ne			S		Unk			Pf	izer
	Epipen				S		Unk			Pf	izer
	Prevaci	d			S		Unk				
	Albutero	ol			S		Unk				
	Synthro	id			S		Unk				



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
27-Nov-2013	9716093	EXPEDITED (15-DAY)			ОТ	CA-MYLAN 2013S1026	-			Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Expired Product Administered; Hypersensitivity; Reac To Excipient	Epipen				S					1	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Dec-2013	9731980	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2013S102	-		14 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure; Expire	d Epipen				S	Intramuscular				1	Mylan
Device Used	Epipen				S	Intramuscular				1	Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2013	9745851	DIRECT			LT				62 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Dyspnoea; Fall; Flushi	ing; Amoxicil	llin			S	Oral				,	Aurobindo
Hyperhidrosis; Hypersensitivity; Loss Consciousness; Respiratory Arrest; Vomiting	Of Epipen				S	Intramuscular					
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Dec-2013	9771154	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2013S102			67 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Amnesia; Blood Press Systolic Increased; Ch					S	Intramuscular				1	Mylan



							• р •				
Discomfort; Chest Pain;		e Hydrochloride Tablets,			S	Oral					
Drug Ineffective; Seizur					_						
	Niacin				С						
	Montelu				С						
	Fluticas				С						
	Diazepa				С						
	Phenob				С						
		lorothiazide			С						
	Levothy				С						
	Calcium				С						
	Vitamin				С						
	Multivita				C C						
	Wilfalax /	/00754501/									
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2013	9771311	EXPEDITED (15-DAY)		Н	)	GB-MYLAN 2013S1027	_			Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Accidental Exposure To Product; Loss Of Consciousness	Epipen				S						Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Dec-2013	9779476	EXPEDITED (15-DAY)		Н	)	US-MYLAN 2013S1028			45 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Anaphylactic Reaction; Device Failure; Drug Ineffective	Epipen				S	Intramuscular					Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Dec-2013	9790574	EXPEDITED (15-DAY)		0	Γ	US-MYLAN 2013S1028			31 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>		<u>Mfr</u>
Device Failure	Epipen 2	2-Pak			S	Intramuscular					Mylan



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FDA Received Date	Case #	Case Type	Hoalth	Prof Ou	teemes	Mfr Contro	N #	503B Facility	Ago	Sex	Country
			neailli			US-ABBVIE		JUSE FACILITY	Age 50 VD		
02-Jan-2014	9793398	EXPEDITED (15-DAY)		ОТ		1183846-00			56 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Injury Associated With	Humira				S	Subcutaneous					
Device; Peripheral Vascular Disorder	Humira Epipen				S S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jan-2014	9691336	EXPEDITED (15-DAY)		HC	)	US-MYLAN 2013S1025			66 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D	ose Epipen	2-Pak			S	Intramuscular				Му	lan
Omission	Lisinopr	il			С	Oral	Took	For Years			
	Mobic				С						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jan-2014	9812793	EXPEDITED (15-DAY)		ОТ		SE-MYLANI 2014S1000				Unknown	SWE
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen				S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jan-2014	9772214	EXPEDITED (15-DAY)		DS	, HO, LT	US-MYLAN 2013S1027			37 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Clostridial Infection;	Epipen	2-Pak			S	Intramuscular				Му	lan
Injection Site Injury; Myositis; Necrotising Fasciitis; Pain In Extremity; Sepsis; Unevaluable Event		ressure Medication erol Medication			C C						



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

16-Jan-2014   9820459   EXPEDITED (15-DAY)   OT   US-MYLANLABS-2014S1000522   6 YR   Male   US-2014S1000522   Mfr   M								•				
Preferred Term	DA Received Date	te Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	Age	Sex	Country
Injection Site Pain; Injury Associated With Device	3-Jan-2014	9820459	EXPEDITED (15-DAY)			ОТ				6 YR	Male	USA
Associated With Device  FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Col   16-Jan-2014   9820490   EXPEDITED (15-DAY)   OT   US-MYLANLABS- 2014\$1000389   2 YR   Unknown   CAl   2014\$1000517   2 US-MYLANLABS- 2014\$1000517   2014\$1000517   Campaigne   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Campaigne   Case #   2014\$1001704   2 YR   Unknown   CAl   2014\$1000517   Campaigne   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Case #   2014\$1001704   2 YR   Unknown   CAl   2014\$1001704   2 YR   Unknown   Cal	eferred Term	Product		Comp.	OTC	Role	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Preferred Term   Product   Case #   Case Type   Health Prof   Draw   Normation   Case Figure   Profice			r			S	Intramuscular				N	<b>1</b> ylan
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Mylan Site Injury; Needle Issue  Epipen S S Mylan Site Injury; Needle Issue  Epipen S S Mfr Control # 503B Facility Age Sex Comp. 16-Jan-2014 9821014 EXPEDITED (15-DAY) OT US-MYLANLABS- 2014S1000517 Freferred Term Product Comp. OTC Comp. OTC Role Route Dosage Text Duration Mfr  Circumstance Or Information Capable Of Leading To Medication Error; Device Failure; Drug Effect Decreased; Hypersensitivity  FDA Received Date S S Intramuscular  Mfr Control # 503B Facility Mylan Mfr  Mylan Mfr  Mylan  Mfr  Mylan  Mfr  Mylan  Mfr  Mylan  Mfr  Mylan  Mfr  Mylan  Male US.  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Mylan  Mylan  Mylan  Male US.  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Mylan  Male US.  Male US.  Mylan  Male US.  Mylan  Male US.  Mylan  Male US.  Mylan  Male US.	DA Received Date	ite Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Foreign Body; Injection Site Injury; Needle Issue  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Control # 503B	3-Jan-2014	9820490	EXPEDITED (15-DAY)			ОТ				2 YR	Unknown	CAN
FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Control #   Comp.   OT   US-MYLANLABS-2014S1000517   S7 YR   Male   US-MYLANLABS-2014S1001704   S8 YR   S8 YR   S8 YR   S8 YR   S8 YR   S8 YR   S9 YR   S8 YR   S9 Y	eferred Term	<u>Product</u>		Comp.	OTC	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
16-Jan-2014 9821014 EXPEDITED (15-DAY) OT US-MYLANLABS-2014S1000517 57 YR Male US.  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Circumstance Or Information Capable Of Leading To Medication Error; Device Failure; Drug Effect Decreased; Hypersensitivity  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Control # 9853381 EXPEDITED (15-DAY) HO US-MYLANLABS-2014S1001704  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Intentional Product Misuse Epipen S Mylan						S					N	1ylan
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Circumstance Or Epipen 2-Pak S Intramuscular Mylan	DA Received Date	te Case#	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Circumstance Or Epipen 2-Pak S Intramuscular Mylan Information Capable Of Leading To Medication Error; Device Failure; Drug Effect Decreased; Hypersensitivity    FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Control #   29-Jan-2014   9853381   EXPEDITED (15-DAY)   HO   US-MYLANLABS-2014S1001704   US-M	3-Jan-2014	9821014	EXPEDITED (15-DAY)			ОТ				57 YR	Male	USA
Information Capable Of Leading To Medication Error; Device Failure; Drug Effect Decreased; Hypersensitivity  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Con 29-Jan-2014 9853381 EXPEDITED (15-DAY) HO US-MYLANLABS- 2014S1001704  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Intentional Product Misuse Epipen S	eferred Term	Product		Comp.	OTC	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
29-Jan-2014 9853381 EXPEDITED (15-DAY) HO US-MYLANLABS- 2014S1001704 Male US.  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Intentional Product Misuse Epipen S Mylan	formation Capable Of eading To Medication rror; Device Failure; Defect Decreased;	le Of ation	-Pak			S	Intramuscular				N	lylan
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Intentional Product Misuse Epipen S Mylan	DA Received Date	ite Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
Intentional Product Misuse Epipen S Mylan	9-Jan-2014	9853381	EXPEDITED (15-DAY)			НО		_			Male	USA
· · · · · · · · · · · · · · · · · · ·	eferred Term	Product		Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
FDA Received Date	tentional Product Mis	Misuse Epipen				S					N	1ylan
	DA Received Date	ite Case#	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2014 9858520 EXPEDITED (15-DAY) OT US-MYLANLABS- Female US. 2014S1001780	1-Jan-2014	9858520	EXPEDITED (15-DAY)			ОТ					Female	USA

Note: If the field is blank, there is no data.

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Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Injection Site Bruising; Injury Associated With Device; Needle Issue; Wrong Technique In Product Usage Proces	Epipen s				S	Intramuscular				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Feb-2014	9868100	EXPEDITED (15-DAY)		(	TC	SE-MYL/ 2014S10			77 YR	Male	SWE
Preferred Term	Product	1	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen				S					Му	lan
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof (	<u>Dutcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Feb-2014	9889633	EXPEDITED (15-DAY)		I	DE	CA-MYL/ 2014S10				Unknown	CAN
Preferred Term	Product	<u>I</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Complication Of Device Insertion	e Epipen				S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911791	NON-EXPEDITED				US-MYL/ 2012S10			73 YR	Male	USA
Preferred Term	Product	į	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Back Pain; Blood Pressure Increas Headache; Product Quality Issue; Tendonis Trigger Finger	,				S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Cor	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911792	NON-EXPEDITED		(	DΤ	US-MYL/ 2013S10			40 YR	Female	USA
Preferred Term	Product	1	Comp.	отс	Role	Route	Dosage 1	Text	Duration	Mfr	



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Drug Ineffective	Epipe Epipe				S S						/lan /lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911793	NON-EXPEDITED		0	Т	US-MYL 2013S10	ANLABS- 001636			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Drug Ineffective	Epipe	en			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911794	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001710			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mfr</u>	:
Accidental Exposure T Product	o Epipe	en			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911795	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001711			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site Pain		en			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911796	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001717			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mfr	:
Insomnia	Epipe	en			S					Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911797	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001719		33 YR	Female	USA



Preferred Term	red Term Product		Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Blood Pressu Increased; Heart Rate Increased; Injection Sit Injury	re				S				M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911798	NON-EXPEDITED					LANLABS- 001720		Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Expired Produ Administered; Wrong Technique In Product Usage Process					S				M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911799	NON-EXPEDITED					LANLABS- 001874		Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<b>Duration</b>	Mf	r
Accidental Exposure T Product	o Epipen				S				M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911800	NON-EXPEDITED					LANLABS- 001875	55 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Injection Site Pain; Product Quality Issue	o Epipen Aleve				S C				M	ylan



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911801	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001876		52 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Anxiety; Flus Palpitations; Product Quality Issue					S C	Subcutaneous	3			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911802	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001877			Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosa	ge Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Feeling Jitter					S					M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911803	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001879			Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosa	ge Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered; Hypoaesthesia; Palpitations; Periphera Coldness	uct				S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911804	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001935			Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Injury Associa With Device					S					M	ylan

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911805	NON-EXPEDITED					LANLABS- 002212			Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product	o Epipen				S					М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911806	NON-EXPEDITED					LANLABS- 002226			Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product	o Epipen				S					М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911807	NON-EXPEDITED					LANLABS- 002232			Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered; Head Discomfort; Injection S Bruising; Nervousness Pain In Extremity; Paraesthesia; Periphe Swelling; Skin Discolouration; Somnolence	uct Site S;				S					M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911808	NON-EXPEDITED					LANLABS- 002236			Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T	o Epipen				S					M	ylan

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Product											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911811	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 002361			Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Accidental Exposure 1 Product	Γο Epipe Epipe				S S						ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911812	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 002417			Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Product Label Issue; Product Storage Error	Epipe	en			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911813	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 002455		4 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Injection Site Haemorrhage; Injection Site Injury; Injection Si Pain	n	en Jr			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911814	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 001915			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Heart Rate Increased	Epipe	en			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911815	NON-EXPEDITED				US-MYL	ANLABS-		50 YR	Female	USA

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# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2013S1002702

Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>		<u>Mfr</u>
Accidental Exposure T Product; Contusion; Product Quality Issue	ō Epiper	n Jr			S						Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911817	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 03452		5 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>		<u>Mfr</u>
Accidental Exposure T Product; Contusion; Peripheral Swelling	ō Epiper	n Jr			S						Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911818	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 06498			Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>		Mfr
Incorrect Route Of Dru Administration; Tremo		า			S		Unk				Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911819	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 003520		4 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>		<u>Mfr</u>
Drug Administration E	rror Epiper Epiper				S S						Mylan Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911821	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 004118			Male	USA

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Preferred Term	Produc	t	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	Mfr	[
Accidental Exposure T Product	o Epipen				S					My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911822	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 004597		55 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	<u>:</u>
Drug Hypersensitivity	Epipen Vioxx				S S					My	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911823	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 004709			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	Text	<b>Duration</b>	Mfr	
Product Quality Issue; Wrong Technique In Product Usage Proces					S					Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911825	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 005481			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	_
Accidental Exposure T Product	o Epipen				S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911826	NON-EXPEDITED					_ANLABS- 005762			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosage	Text	<b>Duration</b>	Mfr	<u>-</u>
Circumstance Or Information Capable O Leading To Medication Error; Product Colour					S		Unk			Му	/lan

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Issue											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911827	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 005769			Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mfr	
Contusion; Injection S Bruising	ite Epipe	n			S		Unk			My	<i>r</i> lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911828	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 005782			Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	:
Euphoric Mood	Epipe	n			S		Unk			Му	<i>r</i> lan
	Benadryl				S		2 Sho	ots		Му	<i>ı</i> lan
	Zanta	С			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911829	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 006117			Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mfr	
Accidental Exposure 1 Product	Γο Epipe	n			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911831	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 006497		9 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure 7 Product	Γο Epipe	n			S		Unk			Му	vlan .



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911832	NON-EXPEDITED					LANLABS- 006500			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia	Epipe	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911833	NON-EXPEDITED					LANLABS- 006682			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Extremity; Prod Quality Issue	duct Epipe	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911834	NON-EXPEDITED					LANLABS- 007124			Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipe	en			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911835	NON-EXPEDITED					LANLABS- 007125			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective; Pain	Epipe	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911839	NON-EXPEDITED					LANLABS- 1007510		12 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T	o Epipe	en			S		Unk		Mylan		lan

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### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product; Injection Site Haemorrhage; Injection

Site Pain	C #	Cons Time	Haalth	Duet (	Ot.a.a.m.a.a	M6- C		FOOD Facility	Ama	Carr	Carreten
FDA Received Date		Case Type	nealth	<u> </u>	<u>Outcomes</u>	•	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911840	NON-EXPEDITED					'LANLABS- 1007741			Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	g <u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Heart Rate Increased; Palpitations		en			S		0.3 M	∕lg, Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911841	NON-EXPEDITED					LANLABS- 1007742			Unknown	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mfr</u>	
Feeling Jittery; Produc Quality Issue	et Epipe	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911843	NON-EXPEDITED					LANLABS- 1007743		60 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	g <u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Pain; Inju Associated With Devic Product Quality Issue		en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911844	NON-EXPEDITED					LANLABS- 1007832			Unknown	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Energy Increa		en			S		Unk			Му	lan



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911845	NON-EXPEDITED				US-MYI 2013S1	LANLABS- 007837		75 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site Pallor		en			S		0.3m	nl, As Needed		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911847	NON-EXPEDITED				US-MYI 2013S1	LANLABS- 008213			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Product Labe Confusion		en Jr			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911850	NON-EXPEDITED				US-MYI 2013S1	LANLABS- 008801			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Injection Site Pain	Epipe	en			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911851	NON-EXPEDITED		0	Т		LANLABS- 009262			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Drug Ineffective	Epipe	en			S		Unk			Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911853	NON-EXPEDITED				US-MYI 2013S1	LANLABS- 009263			Male	USA
Preferred Term	Prod	uct	Comp.	ОТС	Role	Route	Doco	ge Text	Duration	Mfr	

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Injection Site Pain; Product Quality Issue	Epipen	Epipen Cook Towns			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911859	NON-EXPEDITED					LANLABS- 010069			Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product	o Epipen	1			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911860	NON-EXPEDITED					LANLABS- 010262			Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Product Quali Issue					S		Unk			М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911861	NON-EXPEDITED					LANLABS- 010400			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Product Quali Issue		ı			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911862	NON-EXPEDITED					LANLABS- 010604			Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Product Quali		r			s C		Unk			М	ylan



FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol # <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911863	NON-EXPEDITED				US-MYLAN 2013S1010			52 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>ext</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site Haemorrhage; Pain In Extremity		en			S	Intramuscular	1:1000, 0	).3 MI, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol # 5	03B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911864	NON-EXPEDITED				US-MYLAN 2013S1010	-		2 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage T	ext	<b>Duration</b>	Mfr	
Accidental Exposure T Product	o Epipe	en			S	Subcutaneous		nit: 1:2000, 0.3 y Dose: 0.5 Mg)		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol # 5	03B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911865	NON-EXPEDITED				US-MYLAN 2013S1010	-			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>	Mfr	
Contusion; Skin Burnir Sensation	ng Epipe	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol # 5	03B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911866	NON-EXPEDITED				US-MYLAN 2013S1011				Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<u>Duration</u>	Mfr	
Contusion; Injection Si Bruising; Injection Site Pain; Pain; Product Quality Issue		en			S		Unk			Му	lan



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911867	NON-EXPEDITED				US-MYLAN 2013S1011			9 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product By Child	Го Еріре	n			S	Intramuscular	0.3 MI	, 1x/Day, (1:1000)		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911868	NON-EXPEDITED				US-MYLAN 2013S1011	-			Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product	Го Еріре	n			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911869	NON-EXPEDITED				US-MYLAN 2013S1011				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Product Qual Issue		n			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911870	NON-EXPEDITED				US-MYLAN 2013S1012	-		38 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Contusion	Epipe	n			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Conti	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911871	NON-EXPEDITED				US-MYLAN 2013S1012	-			Male	USA
						201001012	2142				

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Accidental Exposure T Product	duct				S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911872	NON-EXPEDITED				US-MYLAN 2013S1012			40 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Injection Site Bruising; Injection Site Pallor; Limb Discomfol		en Jr.			S		1:200 Injecti	0, 0.3 MI, 1 Time (1 on)		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911873	NON-EXPEDITED				US-MYLAN 2013S1013				Unknown	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Fatigue	Epipe	en			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911874	NON-EXPEDITED				US-MYLAN 2013S1013	_			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Pain	Epipe	en			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911875	NON-EXPEDITED				US-MYLAN 2013S1013	_		87 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Drug Ineffective; Expir		en			S	Intramuscular	0.30	/lg, As Needed		М	ylan
Product Administered; Product Quality Issue	пуш	ochlorothiazide			С	Oral	25 Mg	g, 1x/Day			
-	Sertra	aline			С	Oral	100 M	lg, 1x/Day			



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	<u>N</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911877	NON-EXPEDITED					JS-MYLANLABS- 2013S1013702		73 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Accidental Exposure T	o Epi	pen			S		1:10	00, 0.3 MI, 1 Time		N	lylan
Product; Injection Site Coldness; Injection Sit	e Act	onel			С	Oral	150	Mg, Monthly			
Pain		tformin			С	Oral	500	Mg, 2tabs Bid			
	Lisi	nopril W/Hydrochlorothiazide			С	Oral	20/1	2.5 Mg			
	Sim	nvastatin			С	Oral	40 M	/lg Daily			
-	Fina	asteride			С	Oral	5 Mg	g Daily			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	<u> </u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911878	NON-EXPEDITED					JS-MYLANLABS- 2013S1014061			Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product	o Epi	pen			S		Unk			Ν	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	<u>N</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911879	NON-EXPEDITED					JS-MYLANLABS- 2013S1014062			Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product	o Epi	pen			S		Unk			Ν	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	<u>N</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911880	NON-EXPEDITED					JS-MYLANLABS- 2013S1014063			Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product; Expired Produ		pen			S		Unk			N	<b>1</b> ylan

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Administered											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911881	NON-EXPEDITED				US-MYLA 2013S101	-			Unknown	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pain		en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911882	NON-EXPEDITED				US-MYLA 2013S101	-		46 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered		en			S	Unknown	0.3 Mg,	As Needed		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911883	NON-EXPEDITED				US-MYLA 2013S101	-			Unknown	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Expired Product Administered	Epipe	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911884	NON-EXPEDITED				US-MYLA 2013S101			3 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>otc</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child	o Epipe	en Jr			S	Subcutaneous	0.15 Mg Dose	g, 1:2000, 0.3 Ml, 1	I	Му	lan



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							•				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911885	NON-EXPEDITED				US-MYLAN 2013S1014			35 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Asthenia; Migraine; Nausea; Tre	• •	n			S	Intramuscular	0.3 M	1g, As Needed		М	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911886	NON-EXPEDITED				US-MYLAN 2013S1014			3 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mf</u>	r
Accidental Exposure T	Го Еріре	n			S		Unk			М	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Conti	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911887	NON-EXPEDITED				US-MYLAN 2013S1015	_		21 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Intentional Product Mi	suse Epipe	n			S		Unk			М	lylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911888	NON-EXPEDITED				US-MYLAN 2013S1015			36 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mf</u>	r
Accidental Exposure T Product; Pain In Extre Pain In Extremity; Tre	mity;	n Jr			S		1:200	00, 0.3 MI, Single		M	lylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911889	NON-EXPEDITED				US-MYLAN 2013S1015	_			Female	USA

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Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
	·				S	Unknown	0.3 Mg, Unk		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911890	NON-EXPEDITED				US-MYLA 2013S10		62 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug Effect Incomplete	fect Incomplete				S	Intramuscular			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911891	NON-EXPEDITED				US-MYLA 2013S10			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Injection Site Pain	Epipei	า			S		Unk		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911892	NON-EXPEDITED				US-MYLA 2013S10		61 YR	Male	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T	Го Еріреі	n			S	Intramuscular	0.3 Mg, Daily		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911893	NON-EXPEDITED				US-MYLA 2013S10	_	8 YR	Female	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Epipen Jr Product				S	Parenteral	0.3 MI, Single, 1:2000		Му	rlan	



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						20141104					
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911894	NON-EXPEDITED				US-MYLAI 2013S101			30 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Drug Administration Er Product Quality Issue	ror; Epipen				S	Intramuscular	0.3 Mg Dose)	g, As Needed (One		М	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911896	NON-EXPEDITED				US-MYLAI 2013S101	_			Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Pain; Product Quality Issue	Epipen				S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911897	NON-EXPEDITED				US-MYLAI 2013S101				Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product	o Epipen				S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911898	NON-EXPEDITED				US-MYLAI 2013S101	_			Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Product Quali Issue; Psychomotor Hyperactivity					S		Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014	9911899	NON-EXPEDITED				US-MYLAI 2013S101	_		5 YR	Male	USA



<u>Preferred Term</u>	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>		<u>Mfr</u>
Accidental Exposure To Product By Child; Expired Product Administered; Nervousness	roduct By Child; Expired roduct Administered; lervousness				S		Unk			Mylan
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014 9	911900	NON-EXPEDITED				US-MYLAN 2013S1016			Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>		<u>Mfr</u>
Accidental Exposure To Epipen Product					S		Unk			Mylan
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014 9	911901	NON-EXPEDITED				US-MYLAN 2013S1016		60 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>		<u>Mfr</u>
Drug Ineffective; Expired	l Epipen				S	Intramuscular	0.3 Mg, As Needed			Mylan
Product Administered; Insomnia; Restless Legs	Epipen				S	Intramuscular	0.3 Mg, As Needed			Mylan
Syndrome; Somnolence	Epipen				S					Mylan
	Epipen Diphen	hydramine			S S		2 Tablets Taken Per Da	W		Mylan Mylan
	Tramad	-			С	Unknown	Unk	.y		Ž
	Valium				С	Unknown	Unk			
	Pravas	tatin			С	Unknown	Unk			
	Glyburi	de			С	Unknown	Unk			
	Stratte	ra			С	Unknown	Unk			
	Vesica	re			С	Unknown	Unk			
	Pulmic	Pulmicort			С	Unknown	Unk			
	Zolpide	em Tartrate			С	Unknown	Unk			



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911902	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 017488			Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	Mf	<u>.</u>
Accidental Exposure T Product; Injection Site Haemorrhage; Injury Associated With Devic Oedema Peripheral; Product Quality Issue		า			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911903	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 017491			Female	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mf	<u>r</u>
	njection Site Pain; Injury Epipen Jr				S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911904	NON-EXPEDITED		C	T	US-MYI 2013S1	_ANLABS- 017492			Unknown	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective	Epiper	า			S		Unk			M	ylan
	Epiper	า			S		Unk			M	ylan
	Epiper Epiper				S S						ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911905	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 017599		58 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mf	
Injection Site Pain; Injection Site Reaction	Epiper	1	S		0.3 Mg Prn			M	ylan		

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	Benadryl  A Received Date				С		Unk, Prn	l			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contr	ol# <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911906	NON-EXPEDITED				US-MYLAN 2013S1017	-		30 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	Mf	<u>r</u>
Tremor	Epipen				S	Intramuscular	0.3 Mg, A	As Needed		M	ylan
	Epipen				S	Intramuscular	0.3 Mg, <i>i</i>	As Needed		M	ylan
	Epipen Epipen				S S						ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contr	<u>ol#</u> 5	03B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911907	NON-EXPEDITED				US-MYLAN 2013S1017			62 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	Mf	<u>r</u>
Drug Delivery Device Implantation; Drug Effe Incomplete	Epipen ect				S	Intramuscular	0.3 Mg, <i>i</i>	As Needed		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol# <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911908	NON-EXPEDITED		C	T	US-MYLAN 2013S1017				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective	Epipen				S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol# <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911909	NON-EXPEDITED				US-MYLAN 2013S1017			33 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T					S		0.3 Mg, A	As Needed		M	ylan
Product; Energy Increased; Product Qu Issue; Therapeutic	Albutero	bl			С	Respiratory (inhalation)	Unk				

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Note: If the field is blank, there is no data.

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Response Unexpected					С	Oral	Hea	artburn And Dyspepsi	a		
	Hydrod	chlorothiazide			С	Oral	Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911910	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 018268			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ige Text	<b>Duration</b>	Mf	ŗ
Accidental Exposure To Product; Product Quali Issue		1			S		0.3	Mg, Unk		My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911911	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 018269			Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	<u>ige Text</u>	<u>Duration</u>	<u>Mf</u> ı	<u>r</u>
Accidental Exposure To Product; Expired Product; Administered; Injection Site Hypoaesthesia	uct	1			S	Unknown	0.3	Mg, Unk		My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911912	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 018459			Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	<u>ige Text</u>	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure To Product	o Epiper	1			S		Unk			My	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911913	NON-EXPEDITED				US-MYI 2013S1	_ANLABS- 018547			Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ige Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure To Product; Tremor	o Epiper	1			S		Unk	<u> </u>		My	ylan

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911914	NON-EXPEDITED				US-MYLAN 2013S1018			83 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfı	<u>r</u>
Flushing; Pain	Epipe	en			S	Intramuscular	0.30	Mg, Unk		M	ylan
	Fish (	Oil			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911915	NON-EXPEDITED				US-MYLAN 2013S1018			21 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>r</u>
Asthma; Expired Prod	ministered; Injection				S	Intramuscular	0.3 N	Mg, As Needed		M	ylan
dministered; Injection Albuterol ite Pain; Vasoconstriction				С	Respiratory (inhalation)	Prn,	Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911916	NON-EXPEDITED				US-MYLAN 2013S1018	_			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>r</u>
Accidental Exposure T Product	o Epipe	en			S		1 Tir	me		My	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911917	NON-EXPEDITED		0	T	US-MYLAN 2013S1019			53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>r</u>
Chest Discomfort; Dev	vice Epipe	en			S		0.3 N	Иg, Single		M	ylan
Malfunction; Drug Ineffective; Pain In	Bena	dryl			С	Oral	Unk				
Extremity	Albut	erol			С	Oral	Prn				
	Fffex	or Sr			С	Oral	300	Mg Am, 75 Mg At			



							Noon			
	Topai				С	Oral	50 Mg Am, 150 Mg Hs			
	Lantu				С	Subcutaneous	30 Units Am, 30 Units	Pm		
	Nexiu	ım			С	Oral	Qam			
	Ativar				С	Oral	4mg, Unk; Tablet			
	Singu				С	Oral	Hs			
	Trazo	odone			С	Oral	100 Mg, Hs			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911918	NON-EXPEDITED		0	Т	US-MYLANL 2013S10191		53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective	Epipe	en			S		Unk		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911919	NON-EXPEDITED				US-MYLANL 2013S10192			Unknown	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective; Myal	gia Epipe	en			S		Unk		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911920	NON-EXPEDITED				US-MYLANL 2013S10192		51 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T	Го Еріре	en			S	Intramuscular	0.3 Mg, As Needed		M	ylan
Product	Zanta	ıc			С		2x/Day			
	Zyrte	С			С		2x/Day			
	Drade	nisone			С		1x/Day			



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

							ТОРОТ				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911921	NON-EXPEDITED				US-MYLAI 2013S101			51 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Expired Product; Administered; Injection Site Injury; Pain In Extremity; Product Qualissue	uct า	n			S		0.3 Μ <u>ς</u>	g, Unk		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911923	NON-EXPEDITED				US-MYLAI 2013S101			58 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Drug Ineffective	Epipe	n			S	Intramuscular	0.3 Mg	g, As Needed		М	ylan
	Zolpic	dem			С	Oral	10 Mg	, As Needed			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911924	NON-EXPEDITED			НО	US-MYLAI 2013S101			63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Drug Ineffective	Epipe	n			S	Unknown	0.3 Mg	g, As Needed		М	ylan
	Metfo	rmin			С	Oral		g, Unk			
	Lisino	pril			С	Oral	Unk				
	Gaba	pentin			С	Oral	Hs				
	Trazo	done			С	Oral	Hs				
	Benad	dryl			С		25 Mg	x1 Approx <1 Min			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911925	NON-EXPEDITED				US-MYLANLABS- 2013S1019961				Female	USA



Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mf	r
Injection Site Haemorrhage	Epipe	en			S				M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911926	NON-EXPEDITED				US-MYLA 2013S102	=		Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mf	<u>r</u>
Device Failure	Epipe	en 2-Pak			S				M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911927	NON-EXPEDITED				US-MYLA 2013S102	=	4 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product By Child	o Epipe	en Jr			S	Subcutaneous	0.15 Mg, As Needed		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911928	NON-EXPEDITED		C	DΤ	US-MYLA 2013S102			Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective	Epipe	en			S		0.3 Mg, Prn		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911929	NON-EXPEDITED				US-MYLA 2013S102		46 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mf	<u>r</u>
Device Failure	evice Failure Epipen 2-Pak				S	Intramuscular			M	ylan
	Benadryl Allergy Medication				C C					

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### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date 19-Feb-2014	Case # 9911930	Case Type  NON-EXPEDITED	<u>Health</u>	Prof O	utcomes	Mfr Contro		503B Facility	<u>Age</u>	<u>Sex</u> Female	Country USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	<u>Role</u>	2013S10203 <u>Route</u>	Dosage	• Text	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Abnor Erythema; Headache; Oedema Peripheral; Swelling Face					S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911931	NON-EXPEDITED				US-MYLANI 2013S10205	-		63 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen				S	Intramuscular				Му	lan
	Epipen				S	Intramuscular				Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911932	NON-EXPEDITED				US-MYLANI 2013S10205	-		42 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Expired Prod Administered; Hypoaesthesia; Injection Site Coldness; Injection Site Hypoaesthesia; Peripheral Coldness	luct				S					Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	Sex	Country
19-Feb-2014	9911933	NON-EXPEDITED				US-MYLANI 2013S10207			72 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug	Epipen	2-Pak			S	Intramuscular				Му	lan

Note: If the field is blank, there is no data.

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Ineffective											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911935	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 21022			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfı</u>	<u>r</u>
Device Failure	Epipe	n			S					My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911936	NON-EXPEDITED				US-MYL 2013S10				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfı</u>	<u>r</u>
Device Failure; Dyspn Tongue Oedema		n 2-Pak n 2-Pak			S S	Intramuscular Intramuscular				-	ylan ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cor	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911937	NON-EXPEDITED				US-MYL 2013S10	_		32 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mf</u> ı	<u>r</u>
Device Failure	Epipe	n			S	Intramuscular				My	ylan
	Cefdi	nir			С	Oral					
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cor	itrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911938	NON-EXPEDITED				US-MYL 2013S10			273 DAY	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>.</u>
Expired Product Administered; No Adve Event	Epipe erse	n Jr			S					Му	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911939	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 21884			Female	USA

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Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	en			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911940	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 022286			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	en			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911943	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 022608			Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mf	<u>r</u>
Device Failure	Epipe	en			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911944	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 022655			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mf	<u>r</u>
Incorrect Drug Administration Duratio	Epipe n	en			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911945	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 023131			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	en			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911946	NON-EXPEDITED				US-MYL	ANLABS-			Female	USA

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2013S1023394

Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	Mfr	
Nightmare	Epipen				S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	<u>N</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911947	NON-EXPEDITED					JS-MYLANLABS- 2013S1023441			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Injection Site Discolouration; Injectio Site Hypoaesthesia; SI Discolouration	n				S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	<u>N</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911948	NON-EXPEDITED					JS-MYLANLABS- 2013S1023501		52 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Injection Site Pain; Ned Issue	edle Epipen Proair H Symbico Spiriva Lyrica				S C C C					Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	<u>N</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911949	NON-EXPEDITED					JS-MYLANLABS- 2013S1023539		49 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure	Epipen				S					Myl	an



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911950	NON-EXPEDITED				US-MYLA 2013S10			73 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	Mf	<u>.</u>
Muscle Spasms	Epiper	n 2-Pak			S	Intramuscular				M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911951	NON-EXPEDITED				US-MYLA 2013S10	_		19 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	Mf	<u>.</u>
Accidental Exposure T Product; Dizziness; Injection Site Haemorrhage	ō Epiper	n 2-Pak			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014	9911952	NON-EXPEDITED				US-MYLA 2013S10				Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	Mf	<u>.</u>
Accidental Exposure T Product; Unevaluable Event	o Epiper	1			S					M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911953	NON-EXPEDITED				US-MYLA 2013S10			70 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	Mf	1
Blood Pressure Increa Drug Ineffective; Expir Product Administered; Hypersensitivity; Inject Site Haemorrhage	ed	1			S	Intramuscular				M	ylan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Co	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911954	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 024029		47 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Accidental Exposure T Product; Device Malfunction; Injury Associated With Devic	Bysto				S C C	Oral Oral				N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911955	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 024034		39 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Accidental Exposure T Product; Hypoaesthes Injection Site Discolouration; Injectic Site Hypoaesthesia; Injection Site Pain; Sk Discolouration	ia; on				S						Луlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911957	NON-EXPEDITED				US-MYL 2013S10	ANLABS- )24123			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Drug Ineffective; Hypersensitivity; Insor	Epipe nnia Cortic	en costeroid Nos			S S					N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911958	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 024137			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Drug Ineffective; Hot Flush; Hypersensitivity	Epipe	en			S	Intramuscular				N	Mylan



	Benadryl  A Received Date				С	Oral	Takes	Prn.			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911959	NON-EXPEDITED				US-MYLA 2013S102	-			Unknown	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product	o Epiper	ı			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911960	NON-EXPEDITED				US-MYLA 2013S102	_			Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Tremor	Epiper Benad				S S					My My	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911961	NON-EXPEDITED				US-MYLA 2013S102	-			Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mfr</u>	
Injection Site Pain	Epiper	1			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911962	NON-EXPEDITED				US-MYLA 2013S102				Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mfr</u>	
Injection Site Bruising	Epiper	1			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911963	NON-EXPEDITED				US-MYLA 2013S102	-			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	

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Injection Site Haemorrhage	Epipe	n			S				Age Sex Country		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014	9911964	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 124795		42 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Device Failure	Epipe	n 2-Pak			S	Intramuscular				M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911965	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 24897		46 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>ge Text</u>	<b>Duration</b>	Mf	<u>r</u>
Drug Screen Positive	Epipe Trazo Clariti				S C C	Intramuscular				M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911966	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 125166		5 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	n Jr			S					M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014	9911967	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 125312			Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Injection Site Pain; Pain In Extremity		n			S				Mylan		

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Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
9911968	NON-EXPEDITED								Female	USA
<u>Prod</u> ı	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>le Text</u>	<b>Duration</b>	<u>Mfr</u>	
Го Еріре	n			S					Му	rlan
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
9911969	NON-EXPEDITED					_			Female	USA
<u>Prod</u> ı	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Го Еріре	n			S					Му	rlan
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
9911970	NON-EXPEDITED								Male	USA
<u>Prod</u> ı	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>le Text</u>	<b>Duration</b>	<u>Mfr</u>	
Го Еріре :	n			S					Му	rlan
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
9911971	NON-EXPEDITED								Female	USA
<u>Prod</u> ı	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Epipe	n			S					Му	lan
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
9911972	NON-EXPEDITED				US-MYLA				Male	USA
T	9911968  Production  Case # 9911969  Production  Case # 9911970  Production  Case # 9911971  Production  Epipe	Product  Case # Case Type 9911969 NON-EXPEDITED  Product  Fo Epipen  Case # Case Type 9911970 NON-EXPEDITED  Product Fo Epipen  Case # Case Type 9911970 NON-EXPEDITED  Product Fo Epipen  Case # Case Type 9911971 NON-EXPEDITED  Product Epipen  Product Epipen	Product Comp.  Case # Case Type Health 9911969 NON-EXPEDITED  Product Comp.  Case # Case Type Health 9911970 NON-EXPEDITED  Product Comp.  Case # Case Type Health 9911970 NON-EXPEDITED  Product Comp.  Case # Case Type Health 9911971 NON-EXPEDITED  Product Comp.  Case # Case Type Health 9911971 NON-EXPEDITED  Product Comp.  Epipen	Product Comp. OTC  Case # Case Type Health Prof O 9911969 NON-EXPEDITED  Product Comp. OTC  Case # Case Type Health Prof O 9911970 NON-EXPEDITED  Product Comp. OTC  Case # Case Type Health Prof O 9911970 NON-EXPEDITED  Case # Case Type Health Prof O 9911971 NON-EXPEDITED  Product Comp. OTC  Case # Case Type Health Prof O 9911971 NON-EXPEDITED	Product Comp. OTC Role  Case # Case Type Health Prof Outcomes 9911969 NON-EXPEDITED  Product Comp. OTC Role  Fo Epipen S  Case # Case Type Health Prof Outcomes 9911970 NON-EXPEDITED  Product Comp. OTC Role  Fo Epipen S  Case # Case Type Health Prof Outcomes 9911970 NON-EXPEDITED  Product Comp. OTC Role  Epipen S  Case # Case Type Health Prof Outcomes 9911971 NON-EXPEDITED  Product Comp. OTC Role Epipen S  S	9911968   NON-EXPEDITED   US-MYLA 2013S102	9911968 NON-EXPEDITED    Product   Comp.   OTC   Role   Route   Dosage	Product   Comp.   OTC   Role   Route   Dosage Text	Product   Comp.   OTC   Role   Route   Dosage Text   Duration	Product   Comp.   OTC   Role   Route   Dosage Text   Duration   Mfr



Preferred Term	<u>Product</u>		Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Te	<u>xt</u>	<b>Duration</b>	<u>Mfr</u>	•
Accidental Exposure T Product; Injection Site Pain	ct; Injection Site				S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Co	ntrol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911973	NON-EXPEDITED				US-MYL 2013S1	ANLABS- 025684		57 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Discolouration; Pallor		n			S					Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Co	ntrol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911974	NON-EXPEDITED				US-MYL 2013S1	ANLABS- 025724			Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipe	n			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911975	NON-EXPEDITED				US-MYL 2013S1	_ANLABS- 026184		74 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n			S					Му	⁄lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911976	NON-EXPEDITED				US-MYL 2013S1	ANLABS- 026315			Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>	Mfr	
Accidental Exposure To Epipen Product				S					Му	rlan	



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911977	NON-EXPEDITED					LANLABS- 1026502			Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	Mf	<u>r</u>
Drug Hypersensitivity	Epipen				S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911978	NON-EXPEDITED					LANLABS- 1026647			Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Injection Site Bruising	Epipen				S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911979	NON-EXPEDITED					LANLABS- 1026649			Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipen				S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911980	NON-EXPEDITED					LANLABS- 1026701		45 YR	Male	USA
Preferred Term	Produc	<u>ot</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Arthropod Sting; Devic Failure	ce Epipen				S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9911981	NON-EXPEDITED					LANLABS- 1026824			Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipen				S					M	ylan

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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cor	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911982	NON-EXPEDITED				US-MYL/ 2013S10	_		7 YR	Female	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfı</u>	1
Accidental Exposure 1 Product By Child	To Epiper	1			S					My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911983	NON-EXPEDITED				US-MYL/ 2013S10			67 YR	Male	USA
Preferred Term	<u>Produ</u>	ct	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfı</u>	
Accidental Exposure T Product; Expired Prod Administered; Injection Site Hypoaesthesia; Injection Site Pain	luct	n			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911984	NON-EXPEDITED				US-MYLA 2013S10	_		6 YR	Male	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfı</u>	
Drug Ineffective	Epiper	1			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911985	NON-EXPEDITED				US-MYL/ 2013S10				Female	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfı</u>	
Injection Site Discomfo	ort; Epiper	1			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	9911986	NON-EXPEDITED				US-MYLA	AU ADO			Male	USA



Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	•
Accidental Exposure T Product	o Epipe	n			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911988	NON-EXPEDITED				US-MY 2013S1	_ANLABS- 028053			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Injection Site Injury	Epipe	n			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911990	NON-EXPEDITED				US-MY 2013S1	_ANLABS- 028465		40 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n			S	Intramuscula	r			/lan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	Age Sex Country		
19-Feb-2014	9911991	NON-EXPEDITED				US-MY 2013S1	_ANLABS- 028581			Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	:
Accidental Exposure T Product	o Epipe	n			S					Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911992	NON-EXPEDITED				US-MY 2013S1	_ANLABS- 028582			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product	o Epipe	n			S				Mylan		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911993	NON-EXPEDITED				US-MY 2013S1	_ANLABS- 028598			Female	USA

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Preferred Term	<del></del>			OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product	o Epiper	1			S					M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911994	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 028608			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product	o Epiper	1			S					M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911995	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 028609			Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>M1</u>	<u>ir</u>
Accidental Exposure T Product; Expired Devid Used; Injection Site Haemorrhage		1			S					M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911996	NON-EXPEDITED				US-MYL 2013S10	ANLABS- 028796			Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>M1</u>	<u>ir</u>
Product Administered Inappropriate Site	At Epiper	1			S					M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911997	NON-EXPEDITED		(	OT	US-MYL 2012286	ANLABS-PF- 5586		40 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Drug Ineffective	Epiper	1			S		1 Df,	As Needed		M	lylan
	Epiper	<b>,</b>	S		Unk		Mylan				

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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911998	NON-EXPEDITED		0.	Т	US-MYL 2012300	ANLABS-PF- )213			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipe	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9911999	NON-EXPEDITED				US-MYL 2012330	ANLABS-PF- )958			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Heart Rate Increased	Epipe	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912000	NON-EXPEDITED				US-MYL 2013004	ANLABS-PF- 1511			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pain		en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912001	NON-EXPEDITED				US-MYL 2013004	ANLABS-PF- 1520			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product	Го Еріре	en			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912002	NON-EXPEDITED				US-MYL 2013014	ANLABS-PF- 1705			Female	USA

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Accidental Exposure T Product	o Epipei	1			S		Unk			My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014	9912003	NON-EXPEDITED		C	T	US-MYI 201305	LANLABS-PF- 2743			Female	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Dizziness	o Epipei	n Jr			S		0.15 N	Лg		My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014	9912004	NON-EXPEDITED				US-MYI 201306	ANLABS-PF- 1499			Male	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Product Qual Issue		1			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014	9912005	NON-EXPEDITED				US-MYI 201306	ANLABS-PF- 6871			Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Product Labe Issue		1			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2014	9912006	NON-EXPEDITED				US-MYI 201320	ANLABS-PF- 1470			Female	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product By Child	o Epipei	1			S	Unknown	0.3 M	g, Unk		My	ylan



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912007	NON-EXPEDITED		0.	Т	US-MYLAN 201321431	NLABS-PF- 19			Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Produ	uct Epipe	en			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912008	NON-EXPEDITED		DI	E	US-MYLAN 201322631	NLABS-PF- 10			Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipe	en			S		3 Df,	Unk		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912009	NON-EXPEDITED		0.	Т	US-MYLAN 201327218	NLABS-PF- 30		45 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Produ Packaging Quantity Iss		en			S	Intramuscular	0.3 M	g, Unk		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912010	NON-EXPEDITED				US-MYLAN 201327406				Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Product; Expired; Injection Administered; Injection Site Paraesthesia; Inju Associated With Device Paraesthesia	uct Alleg  Singu	ra ulair			S C C		Unk			Му	<b>r</b> lan



FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	Age	Sex	Country
19-Feb-2014	9912012	NON-EXPEDITED	<u></u>			US-MYLAN 201327954	LABS-PF-	<u>5552 : us,</u>	<u>go</u>	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfı	1
Feeling Abnormal; Flushing; Nausea	Epipe Benad				S C	Intramuscular	0.3 Mg	g, Unk		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912013	NON-EXPEDITED				US-MYLAN 201327954				Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>-</u>
Accidental Exposure T Product; Product Qual Issue					S S		Unk			•	ylan ylan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912014	NON-EXPEDITED				US-MYLAN 201327963	-		35 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	
Accidental Exposure T Product; Injection Site Paraesthesia		n Jr			S	Intramuscular	0.15 N	lg, Unk		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912015	NON-EXPEDITED				US-MYLAN 201328205			40 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mf	1
Dyspnoea; Injection Si	ite Epipe	n			S		0.3 Mg	g, Unk		My	/lan
Nodule; Injection Site Pain; Palpitations; Pro Administered At Inappropriate Site	duct Estro	gens			С		Over - Medic	Γhe Counter ation			



							•				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912016	NON-EXPEDITED				US-MYLAN 201328632	NLABS-PF- 25			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Injection Site Discolouration; Injection Site Pain; Injection Site Pallor	uct	en			S		0.3 M	g, Unk		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
19-Feb-2014	9912017	NON-EXPEDITED				US-MYLAN 201328636	NLABS-PF- 60		3 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	:
Accidental Exposure 7 Product	o Epipe	en			S	Intramuscular	0.3 M	g, Unk		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912018	NON-EXPEDITED				US-MYLAN 201329328	NLABS-PF- 37			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure 7 Product	o Epipe	en			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912019	NON-EXPEDITED				US-MYLAN 201329328	NLABS-PF- 38			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Accidental Exposure T	o Epipe	en			S	Unknown	0.3 M	g, Unk		Му	vlan .



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912020	NON-EXPEDITED				US-MYL 2013293	ANLABS-PF- 3300			Male	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipen				S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912021	NON-EXPEDITED				US-MYL 2013294	ANLABS-PF- 1876			Female	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Injection Site Pain	Epipen				S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Feb-2014	9912022	NON-EXPEDITED				US-MYL 2013294	ANLABS-PF- 1958			Female	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Hypoaesthes					S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Feb-2014	9914064	EXPEDITED (15-DAY)			ОТ	GB-MYL 2014S10	ANLABS- 003389		7 YR	Male	GBR
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Wou					S	Intramuscular				Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Feb-2014	9921948	DIRECT			HO, LT				60 YR	Male	USA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Drug Monitori	ing Epipen				S					My	rlan

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Procedure Not Performed; Dyspnoea; Inappropriate Schedule Of Drug Administration; Loss Of Consciousness; Pulse

Absent; Underdose											
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Mar-2014	9981376	EXPEDITED (15-DAY)		(	T		LANLABS- 1004944		7 YR	Male	FRA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Device Failure; Wrong Technique In Product Usage Process	Epipen				S					Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Mar-2014	9995761	DIRECT	Υ	(	DT					Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mfr	
Device Malfunction; Inj Associated With Devic					S					Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Mar-2014	10006021	EXPEDITED (15-DAY)		(	T		LANLABS- 1004916			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mfr	
Drug Effect Decreased Expired Product Administered	l; Epipen				S					Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Mar-2014	10008394	EXPEDITED (15-DAY)		(	TC		LANLABS- 1005559			Female	SWE
Preferred Term	Produc	t	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen				S					Mv	rlan

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# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Mar-2014	10021420	EXPEDITED (15-DAY)		0	Т	GB-MYLAN 2014S1006				Female	GBR
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mf	<u>r</u>
Expired Product Administered; No Adve Event	Epipe erse	en			S					My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
26-Mar-2014	10038369	EXPEDITED (15-DAY)		0	Т	US-MYLAN 2014S1005			58 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure; Loss O Consciousness	of Epipe	en 2-Pak			S	Intramuscular				My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Mar-2014	10039183	EXPEDITED (15-DAY)		0	Т	US-MYLAN 2014S1006	_		55 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Device Failure	Epipe	en 2-Pak			S	Intramuscular				My	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Mar-2014	10048603	EXPEDITED (15-DAY)		0	Т	US-MYLAN 2014S1006	_		15 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u> ı	<u>r</u>
Anxiety; Injection Site		en 2-Pak			S	Intramuscular				M	ylan
Laceration; Needle Iss	ue Xope	nex			С	Respiratory (inhalation)					
	Singu				С	Oral	Taken	For Years			
	Pulm	icort			С	Respiratory (inhalation)	Taken	For Years			



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
31-Mar-2014	10048672	EXPEDITED (15-DAY)		(	T	US-MYLANI 2014S10040		61 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Incorrect Dose Administered; Stress; Wrong Technique In Product Usage Proces	Epipei	n 2-Pak n 2-Pak n 2-Pak			\$ \$ \$	Intramuscular Intramuscular Intramuscular			N	1ylan 1ylan 1ylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Apr-2014	10064470	EXPEDITED (15-DAY)		(	T	AU-MYLANI 2014S10069	_		Female	AUS
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Anaphylactic Reaction Product Package Associated Injury	; Epipei	า			S				M	lylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2014	10073664	NON-EXPEDITED				US-PFIZER 2014102042		70 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Fatigue; Injection Site	Epipei	n			S	Intramuscular			Р	fizer
Pain; Nervousness	Solu-N	Medrol			S	Intravenous (not otherwise specifie	ed)		Р	fizer
	Predn	isone			S	Oral				
	Lantus	3			С	Subcutaneous				
	Novolo	og			С	Subcutaneous				
	Keppr	a			С	Oral				
	Metfor	min			С	Oral				
	Lipitor				С	Oral				



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Apr-2014	10074611	EXPEDITED (15-DAY)		(	ОТ	US-MYLAN 2014S1008			39 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	<u>.</u>
Device Failure	Epipen 2	2-Pak			S	Intramuscular				My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Apr-2014	10077848	EXPEDITED (15-DAY)		(	ОТ	US-MYLAN 2014S1008				Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mfr	<u>.</u>
Device Failure; Injectic Site Bruising; Injection Pain					S					Му	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Apr-2014	10079920	EXPEDITED (15-DAY)		(	ТС	US-MYLAN 2014S1008			58 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mfr	1
Device Failure	Epipen 2	2-Pak			S	Intramuscular				My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2014	10089352	EXPEDITED (15-DAY)		I	НО	AU-MYLAN 2014S1008	_			Male	AUS
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	Mfr	1
Apparent Death; Asph Cardiac Arrest; Fall; Hypersensitivity; Need Issue; Pharyngeal Oedema	•				S					My	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-May-2014	10159806	EXPEDITED (15-DAY)		(	OT	JP-MYLAN	ARS-		89 YR	Male	JPN

Note: If the field is blank, there is no data.

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Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Injection Site Pain; Product Quality Issue	Epipen Bosmin	/00003901/			S C	Intramuscular	0.3 Mg	, Daily		My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-May-2014	10170269	EXPEDITED (15-DAY)		C	T	CA-MYLANI 2014S10101			4 YR	Male	CAN
Preferred Term	<u>Produc</u>	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product By Child; Limb Injury					S					My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-May-2014	10176732	EXPEDITED (15-DAY)		F	Ю	US-MYLANI 2014S10106			59 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure	Epipen 2	2-Pak			S	Intramuscular				M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2014	10191271	EXPEDITED (15-DAY)		C	T	DE-MYLANI 2014S10119	_		70 YR	Female	DEU
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mf	<u>r</u>
Device Failure	Epipen				S	Intravenous (not otherwise specific	ed)			My	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>utcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2014	10200177	EXPEDITED (15-DAY)		F	IO, OT	SE-MYLANI 2014S10119			80 YR	Male	SWE
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	Mf	<u>r</u>
Device Failure; Drug Ineffective	Epipen				S					My	ylan



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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jun-2014	10230606	EXPEDITED (15-DAY)			НО	CA-MYLAN 2014S1012	_			Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen				S					Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2014	10250460	DIRECT								Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Drug Dispensing Error Intercepted Drug Dispensing Error	; Epi Pen				S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jun-2014	9681902	EXPEDITED (15-DAY)			ОТ	JP-MYLANI 2013S1025			68 YR	Male	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Dyspnoea;	Epipen				S	Intramuscular	Unk			My	lan
Haemorrhage Subcutaneous; Injectio	Norvaso	;			С	Oral					
Site Pain; Oedema Peripheral; Oral Pain	Diovan				С	Oral					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jun-2014	9695174	EXPEDITED (15-DAY)			ОТ	JP-MYLANI 2013S1025				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Expired Product Administered	Epipen				S	Intramuscular	Unk			Myl	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2014	10257461	DIRECT			ОТ				49 YR	Female	USA

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Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>		<u>Mfr</u>
Discomfort; Gait Disturbance; Gait Inab Injection Site Pain; Injection Site Swelling; Muscle Spasms	ility;	Autoinjector 0.3 Mg			S		0.3mg, As Needed, Into The Muscle			Mylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2014	10256799	EXPEDITED (15-DAY)		I	_T	US-MYLANL 2014S10144	=		Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>		Mfr
Device Malfunction; Dyspnoea; Injury Associated With Devic Pharyngeal Oedema; Swollen Tongue	Epipen e;				S	Intramuscular				Mylan
FDA Received Date	Case #	Case Type	<b>Health</b>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<b>Country</b>
26-Jun-2014	10233878	EXPEDITED (15-DAY)		(	TC	US-MYLANL 2014S10135		28 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Accidental Exposure T Product; Expired Product Administered; Injection Site Ischaemia	uct	2-Pak			S					Mylan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2014	10273594	DIRECT	Υ	(	TC			5 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Abdominal Pain; Coug Dysphonia; Food Aller Injury Associated With Device; Urticaria; Wheezing	gy;	Jr			S					Mylan



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jul-2014	10274908	EXPEDITED (15-DAY)		(	TC	US-MYLANL 2014S10153	_	57 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Effect Decreased Feeling Jittery; Heart F Decreased; Urticaria		2-Pak			S	Intramuscular			Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2014	10283757	EXPEDITED (15-DAY)		(	ЭТ	US-MYLANL 2014S10158	=	12 YR	Female	USA
<u>Preferred Term</u>	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure; Drug Ineffective; Dyspnoea; Pharyngeal Oedema	Epipen Prednis				S C	Intramuscular			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2014	10285021	EXPEDITED (15-DAY)		(	ЭТ	US-MYLANL 2014S10156		5 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Anaphylactic Reaction Drug Effect Decreased Injection Site Injury; Needle Issue		Jr 2-Pak Jr 2-Pak			S S					rlan rlan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2014	10305805	DIRECT		l	_T, OT			52 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Dyspnoea; Hypoaesthe Eye	esia Epipen				S	Intramuscular	Autoinjector Once Into T Muscle	he	Sa	nofi



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2014	10143006	EXPEDITED (15-DAY)		DI	Ξ	US-MYLANL/ 2013221268	ABS-PF-		13 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	M	<u>fr</u>
Cardiac Arrest; Drug Ineffective; Dyspnoea; Laryngeal Oedema; Respiratory Arrest; Vomiting	Epipen				S		3 Еру	Pens		N	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2014	10273180	EXPEDITED (15-DAY)		0	Γ	DE-MYLANL/ 2014S101541			2 YR	Male	BRA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure; Drug Ineffective; No Adverse Event	Epipen e				S					N	lylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2014	10302880	EXPEDITED (15-DAY)		0	Γ	ES-MYLANLA 2014S101488	-		11 YR	Female	ESP
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure	Epipen				S					N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2014	9899483	EXPEDITED (15-DAY)		0	Γ	US-MYLANL/ 2014S100297	-		2 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Injury Associated With Device		Jr 2-Pak Jr 2-Pak			S S	Intramuscular Intramuscular					1ylan 1ylan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jul-2014	10215239	EXPEDITED (15-DAY)		0	Γ	US-MYLANL 2014S10124	=	33 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>!</u>	<u>Mfr</u>
Device Failure; Dyspno Pharyngeal Oedema; Tremor	oea; Epipen Epipen				S S					Mylan Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2014	10276583	EXPEDITED (15-DAY)		0	Γ	CA-MYLANL 2014S10151	=	30 YR	Male	CAN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>!</u>	<u>Mfr</u>
Anaphylactic Reaction Drug Dispensing Error Drug Ineffective; Wron Technique In Product Usage Process	•••				S					Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2014	10309460	EXPEDITED (15-DAY)		0	Γ	US-MYLANL 2014S10166	=		Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>!</u>	<u>Mfr</u>
Accidental Exposure T Product; Limb Injury; Wrong Technique In Product Usage Proces					S					Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2014	10312147	EXPEDITED (15-DAY)		0	Γ	US-MYLANL 2014S10163	=	77 YR	Male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	1	<u>Mfr</u>
TICICITCA TCITII										



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

						(inhalation)				_
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jul-2014	10313751	EXPEDITED (15-DAY)			HO, OT	US-SHIRE- US201403903		53 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Firazy	vr			S	Subcutaneous	30 Mg, As Req'D		Shii	е
Dyspnoea; Hereditary Angioedema; Rash;	Epipe	n			S	Unknown	Unk, One Dose			
Wheezing	Epipe	n			S	Unknown	Unk, Unknown			
	Other	Therapeutic Products			С	Unknown	Unk, Unknown			
	Predn	isone			С	Unknown	Unk, Unknown			
	Kalbit	or			С	Unknown	Unk, Unknown			
	Albute	erol Hfa			С	Unknown	Unk, Unknown			
	Pepci	d /00305201/			С	Unknown	Unk, Unknown			
	Dyazi	de			С	Unknown	Unk, Unknown			
	Potas	sium CI			С	Unknown	Unk, Unknown			
	Clona	zepam			С	Unknown	Unk, Unknown			
	Zyrted	;			С	Unknown	Unk, Unknown			
	Armou	ur Thyroid			С	Unknown	Unk, Unknown			
	Acido	philus			С	Unknown	Unk, Unknown			
	Magn	esium			С	Unknown	Unk, Unknown			
	Benad	dryl /00000402/			С	Unknown	Unk, Unknown			
	Ibupro	ofen			С	Unknown	Unk, Unknown			
	Tylend	ol /00020001/			С	Unknown	Unk, Unknown			
	Vitam	ins Nos			С	Unknown	Unk, Unknown			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2014	10337315	EXPEDITED (15-DAY)			ОТ	US-MYLANLAE 2014S1017031	3S-	59 YR	Female	USA
Preferred Term	<u>Product</u>			OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr	



Device Failure	Epipe	n 2-Pak			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2014	10359261	DIRECT							1 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Injury Associated With Device; Panic Reaction Skin Discolouration; Wrong Patient Received Medication	n;	en Jr			S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Aug-2014	10365132	DIRECT			ОТ				4 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Heart Rate Increased; Laceration; Respiratory Rate Increased	Epipe	n Jr			S						
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2014	10368752	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014S1017				Unknown	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	.3 N	lg,Prn		Му	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2014	10368811	EXPEDITED (15-DAY)			DE	GB-MYLAN 2014M1000				Unknown	GBR
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mfr</u>	
Hypersensitivity	Enino	n Auto-Injector 0.3 Mg			S		Unk			My	lan

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	itcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Aug-2014	10375159	DIRECT							3 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure To Product; Circumstance On Information Capable Of Leading To Device Use Error; Haemorrhage; Injug Associated With Device; Palpitations	Or				S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Aug-2014	10380875	DIRECT	Υ	ОТ	-				3 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Laceration; Urticaria	Epipen .	Jr			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Aug-2014	10381533	EXPEDITED (15-DAY)		ОТ	-	US-MYLANLA 2014M100046	-			Unknown	USA
<u>Preferred Term</u>	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Blood Pressure Increase Hypokalaemia; Therapeutic Response Unexpected; Vasoconstriction	ed; Epipen .	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Aug-2014	10394539	EXPEDITED (15-DAY)		LT		CA-MYLANLA 2014S101790				Unknown	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen				S		Unk			Му	lan

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# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Aug-2014	10337332	EXPEDITED (15-DAY)		(	ОТ	CA-MYLANI 2014S10172				Male	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; Needle Issue	e Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Aug-2014	10403217	EXPEDITED (15-DAY)		(	ОТ	JP-MYLANL 2014M1002				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Expired Product Administered; Feeling Abnormal	Epipen				S	Intramuscular	Unk			Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Aug-2014	10406154	DIRECT								Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Drug Dispensing Error		Jr. Auto-Injector			S S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Aug-2014	10406581	EXPEDITED (15-DAY)		(	ОТ	US-MYLANI 2014M1001	-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	Mfr	
Device Failure; Drug Ineffective; Pharyngeal Oedema; Urticaria		Auto-Injector			S	Intramuscular	0.3 M	g, Once		Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country



							- 1				
Preferred Term	Produc	t	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Expire Product Administered	ed Epipen	Auto-Injector			S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
26-Aug-2014	10411302	EXPEDITED (15-DAY)		(	DΤ	US-MYLAN 2014M1001				Unknown	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mfr	
Expired Product Administered; Feeling Abnormal	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Aug-2014	10417315	EXPEDITED (15-DAY)		ŀ	Ю	BE-MYLAN- 2013S1023				Unknown	BEL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective; Paraesthesia; Wrong Technique In Product Usage Process	Epipen Adrenal	ine			S S	Intramuscular	Unk .8 Mg,	Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Aug-2014	10417316	EXPEDITED (15-DAY)		L	.T	DK-MYLAN 2013S1001				Unknown	DNK
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug Ineffective	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Sep-2014	10429991	EXPEDITED (15-DAY)		(	DΤ	US-MYLAN 2014M1002	-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular 0.3 MI, Qd		Od		Myl	an

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Sep-2014	10440715	DIRECT	Υ						40 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered By Devic Needle Issue	Epi Pe e; Predni Doxy				S C C						
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Sep-2014	10441808	EXPEDITED (15-DAY)			DE	US-MYLANLA 2014M100294				Unknown	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Intentional Product Mis	suse Epiper	n Auto-Injector			S					Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Sep-2014	10441810	EXPEDITED (15-DAY)			ОТ	US-MYLANLA 2014M100287				Unknown	USA
Preferred Term	Produ	ıct	Comp.	OTC	<u>Role</u>	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Anaphylactic Reaction; Device Failure; Drug Ineffective	• •	n Auto-Injector ileptics			S C	Intramuscular	0.3 Mg	ı, Prn		My	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Sep-2014	10369299	EXPEDITED (15-DAY)			ОТ	JP-MYLAN- \$E2B0000047	335			Unknown	JPN
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product By Child; Gait Disturbance; Injection S Pain; Restlessness		n Injection 0.15mg			S	Subcutaneous	.15 Mg	ı,Unk		My	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Sep-2014	10450765	EXPEDITED (15-DAY)			НО	GB-MYLAN- 2014M100417	<b>'</b> 0			Unknown	GBR

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Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>		
Device Failure; Drug Ineffective	Epipe	n Auto-Injector 0.3 Mg			S		Separa	ate Dosages: 1		Му	an	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
26-Sep-2014	10478391	EXPEDITED (15-DAY)		C	T	US-MYLAN 2014M1004	-			Unknown	USA	
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>		
Device Failure; Drug Ineffective; Pharyngea Oedema; Swollen Ton	al	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	an	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
09-Oct-2014	10423652	EXPEDITED (15-DAY)		C	T	JP-MYLANI 2014M1002				Unknown	JPN	
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>		
Accidental Exposure T Product; Expired Product; Expired Product; Expired Production Si Administered; Heart R Increased; Injection Si Erythema; Injection Site Pain; Injection Site Swelling	uct ate ite	n			S		Unk			Му	lan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
09-Oct-2014	10507403	EXPEDITED (15-DAY)		C	T	SE-MYLAN 2014M1005				Unknown	SWE	
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>		
Adverse Event; Reacti To Excipient		en /00003901/			S S S		Unk			Му	lan	
					C C C		J					



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Felodi	pine			С						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Oct-2014	10507886	EXPEDITED (15-DAY)		0	т	BE-MYLAN 2014M100	-			Unknown	BEL
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	g <u>e Text</u>	<b>Duration</b>	Mf	<u>r</u>
Device Failure	Epiper	า			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Oct-2014	10521488	DIRECT	Υ							Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	Mf	ŗ
Accidental Exposure T Product; Injury Associa With Device; Skin Discolouration; Vasoconstriction		n (Epinephrine) olamine Mesylate			S S						
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Oct-2014	10521642	DIRECT	Υ							Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	Mf	ŗ
Anxiety; Laceration; Needle Issue; Scar; Wrong Technique In Product Usage Proces	Epiper ss	n Jr			S						
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Oct-2014	10530920	DIRECT	Y						3 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	Mf	ŗ
Injection Site Laceration	on; Epiper	n Jr			S						



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Oct-2014	10532720	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014M1007				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Oct-2014	10516184	EXPEDITED (15-DAY)			НО	GB-MYLAN 2014M1007				Unknown	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Under	dose Epipen	Auto-Injector 0.3 Mg			S		0.3 M	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2014	10465106	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014M1004				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure		Auto-Injector Auto-Injector			s s	Intramuscular	0.3 M	g, Prn		Myl Myl	
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Oct-2014	10538179	EXPEDITED (15-DAY)			ОТ	SE-MYLAN 2014M1007				Unknown	SWE
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Hypersensitivity	Epipen Thacap	zol			S S		Unk			Myl	an
	Prednis	olone			С		5 Mg,	Qd			
	Prednis Cortisor Anapen Selokee Selokee Felodipi	ne /00003901/ en en			000000						

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Oct-2014	10548915	EXPEDITED (15-DAY)			ОТ	CA-MYLAN 2014M100	_			Unknown	CAN
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product By Child; Injur Associated With Devic	у	n Jr			S					My	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Oct-2014	10548949	EXPEDITED (15-DAY)			ОТ	CA-MYLAN 2014M100	_			Unknown	CAN
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epiper	n			S		Unk			My	lan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Oct-2014	10552860	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014M100				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Device Failure; Drug D Omission; Dysphagia	ose Epiper	n Auto-Injector			S	Intramuscular	0.3 M	lg, Prn		My	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Oct-2014	10552884	EXPEDITED (15-DAY)			НО	US-MYLAN 2014M100	_			Unknown	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Expired Product		n Auto-Injector			S	Intramuscular	0.3 N	lg, Once		Myl	an
Administered; Incorrec Dose Administered:	t Albute	erol /00139501/			С		Unk				
Injection Site Injury;	Adder	all			С		Unk				
Tachycardia	Singul	air			С		Unk				
	Zyrtec				С		Unk				



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Oct-2014	10337323	EXPEDITED (15-DAY)		0.	Γ	US-MYLAN 2014S1017				Unknown	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Product Administered		en Auto-Injector			S		.3 Mg	,Once		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Nov-2014	10561239	EXPEDITED (15-DAY)		0.	Г	US-MYLAN 2014M100				Unknown	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epip	en Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Nov-2014	10561265	EXPEDITED (15-DAY)		0.	Г	US-MYLAN 2014M100				Unknown	USA
Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epip	en Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	⁄lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Nov-2014	10563792	EXPEDITED (15-DAY)		0.	Γ	US-PFIZEI 201425856			61 YR	Female	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Anxiety;	o Epip	en			S		0.3 M Inject	g, Prn (Take 2 ions)		Pfi	zer
Dizziness; Drug Interaction; Dyspepsia:	Levo	thyroxine Sodium			S		Unk	-		Pfi	zer
Dyspnoea; General	Exfo	rge			С		Unk				
Physical Health Deterioration; Headach	Proto	onix			С		Unk				
Heart Rate Increased; Hyperhidrosis;	Estro	ogens			С		Unk				

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Palpitations; Pharyngeal Prednisone C Unk

Oedema; Swollen Tong Tremor		uriisorie			O		Unk			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol # 503B Facilit	y <u>Age</u>	<u>Sex</u>	Country
05-Nov-2014	10437621	EXPEDITED (15-DAY)		C	T	US-MYLAN 2014M1002	_		Unknown	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Anal Incontinence; Anxiety; Asthenia; Body Temperature Increased Chills; Confusional State Feeling Abnormal; Fee Cold; Hyperhidrosis; Livedo Reticularis; Nausea; Nervousness; Presyncope; Pruritus; Retching; Tremor	y Epip d; Oph te; Ben	pen Auto-Injector pen Auto-Injector hthalmologicals hadryl /00000402/			S S C C	Intramuscular	0.3 Mg, Prn Unk Unk		Му	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol # 503B Facilit	y <u>Age</u>	<u>Sex</u>	Country
05-Nov-2014	10567239	EXPEDITED (15-DAY)		C	T	GB-MYLAN 2014M1009	=		Unknown	GBR
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product By Child; Emotional Distress; njection Site Pain	о Еріן	oen Auto-Injector 0.3 Mg			S		Unk Mg, Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol# 503B Facilit	y <u>Age</u>	<u>Sex</u>	Country
07-Nov-2014	10571593	EXPEDITED (15-DAY)		C	T	US-MYLAN 2014M1009	_		Unknown	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Dmission	ose Epip	oen Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control i	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Nov-2014	10571604	EXPEDITED (15-DAY)			ОТ	US-MYLANLAI 2014M100414	_		Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Anxiety;	o Epipe	n Auto-Injector			S		0.3 Mg, Prn (Take 2 Injections)		Му	rlan
Dizziness; Drug Interaction; Dyspepsia;	Exforg	je			С		Unk			
Dyspnoea; Headache;		nix			С		Unk			
Heart Rate Increased;	Estrog	jens			С		Unk			
Hyperhidrosis; Palpitations; Pharynge	al Levoth	nyroxine			С		Unk			
Oedema; Swollen Tong Tremor; Unevaluable Event		isone			С		Unk			
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Nov-2014	10574703	EXPEDITED (15-DAY)			DS, OT	US-MYLANLAI 2014M100588		26 YR	Female	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Contusion; Dizziness; Dysstasia; Headache; Hypoaesthesia; Injectio Site Oedema; Migraine Nausea; Skin Discolouration; Vomitir	on 9;	n Jr. Auto-Injector			S		Unk, Prn		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Nov-2014	10447251	EXPEDITED (15-DAY)			LT, OT	US-MYLANLAI 2014M1004189	_		Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug Effect Decreased	Epipe	n Jr. Auto-Injector			S	Intramuscular			Му	vlan .



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Nov-2014	10593118	EXPEDITED (15-DAY)		C	T	US-MYLANI 2014M1010			Unknown	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure		en Auto-Injector en Auto-Injector			S S	Intramuscular	0.3 Mg, Prn		My My	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Nov-2014	10593124	EXPEDITED (15-DAY)		C	T	US-MYLANI 2014M1010			Unknown	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Nov-2014	10609985	EXPEDITED (15-DAY)	Υ		E, HO	IMP_08219_	_2014	49 YR	Female	AUS
Preferred Term	Prod	l <u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Amputation; Gas	Prom	ethazine (Promethazine)			S		Until Not Continuing	1 DAY		
Gangrene	Epipe	en (Epipen) (Not Specified)			S	Subcutaneous Intramuscular	Not Continuing Not Continuing	1 DAY 2 YR		
	Predi	nisone			С					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Dec-2014	10600287	EXPEDITED (15-DAY)		L	.T	JP-MYLANL 2014M1011			Unknown	JPN
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Injec Site Haemorrhage; Injection Site Pain		en			S		0.15 Mg, Unk		Му	an



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Dec-2014	10589050	EXPEDITED (15-DAY)		Н	0	US-ROCHE	-1491028		12 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Dyspnoea	Xolair Epipen	ı			S S	Subcutaneous Unknown					
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2014	10637818	EXPEDITED (15-DAY)		Н	O, LT, OT	GB-MYLAN 2014M1012	-			Unknown	GBR
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; Expired Device Used; No Adve Event		ukast solone amol			s 	Intramuscular	.3 Mg	, Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2014	10637847	EXPEDITED (15-DAY)		0	Т	GB-MYLAN 2014M1013	-			Unknown	GBR
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; No Adverse Event	Epipen	Auto-Injector 0.3 Mg			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2014	10639346	EXPEDITED (15-DAY)		0	Т	US-MYLAN 2014M1012	_			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 M	n Prn		Mv	lan

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2014	10639350	EXPEDITED (15-DAY)		C	T	US-MYLAN 2014M1012				Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Injection Site Injury	Epipen	Jr. Auto-Injector			S		Unk, F	Prn		Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Dec-2014	10646093	EXPEDITED (15-DAY)		C	T	US-MYLAN 2014M1013	_			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure To Product; Expired Product; Administered; Injection Site Injury	uct	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Dec-2014	10647655	EXPEDITED (15-DAY)		C	T	US-MYLAN 2014M1013	_			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure To Product; Expired Devic Used; Injection Site Haemorrhage		Jr. Auto-Injector			S		Unk			Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Dec-2014	10651524	EXPEDITED (15-DAY)		C	DΤ	US-MYLAN 2014M1013	_			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Myl	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	10656393	EXPEDITED (15-DAY)		_	)T	US-MYLAN				Unknown	USA

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Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Vasoconstriction		en Jr. Auto-Injector			S		Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Dec-2014	10657430	EXPEDITED (15-DAY)		C	T	US-MYLANI 2014M1013			Unknown	USA
Preferred Term	Prod	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epip	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Dec-2014	10662168	EXPEDITED (15-DAY)		L	Т	US-MYLANI 2014M1013			Unknown	USA
Preferred Term	Proc	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epip	en Auto-Injector			S	Subcutaneous	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Dec-2014	10568779	EXPEDITED (15-DAY)		C	T	US-BAXTEF 2014BAX06		52 YR	Female	USA
Preferred Term	Proc	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Anaphylactic Reaction	; Gam	magard Liquid			S	Subcutaneous			Bax	xter
Angioedema; Blood Pressure Increased; D	ark Gam	magard Liquid			S	Subcutaneous			Bax	xter
Circles Under Eyes; Diarrhoea; Dizziness; Food Allergy; Food Intolerance; Headache Malaise; Muscle Spasi Unevaluable Event; Ye Skin	ms;	en			S	Unknown				



FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Dec-2014	10671419	EXPEDITED (15-DAY)		(	DΤ	SE-MYLAN 2014M1014				Unknown	SWE
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen				S		.3 Mg,	Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u> Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Dec-2014	10677005	EXPEDITED (15-DAY)		L	_T	US-MYLAN 2014M1014				Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Dec-2014	10653471	EXPEDITED (15-DAY)		[	DE	US-MYLAN 2014M1013				Unknown	MEX
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S		Unk			Myl	an
	Epipen	Auto-Injector			S					Myl	an
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof C	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
05-Jan-2015	10691214	EXPEDITED (15-DAY)		(	DΤ	AU-MYLAN 2014M1015				Unknown	AUS
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Reaction; Headache; Pyrexia; Vomiting	Epipen Injector	Jr Adrenaline Auto-			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jan-2015	10711201	EXPEDITED (15-DAY)		(	TC	JP-MYLAN 2014S1012			66 YR	Female	JPN
Preferred Term	Produc		Comp.	ОТС	Role	Route	Dosage		Duration	Mfr	

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Product Administered At Inappropriate Site; Product Quality Issue: Soft Tissue Epipen

Intramuscular

S

Unk

Mylan

FDA Received Date	Case #	Case Type	<b>Health</b>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
15-Jan-2015	10530371	EXPEDITED (15-DAY)			DE	AU-MYLAN 2014M1007				Unknown	AUS
Preferred Term	<u>Produ</u>	ıct	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mfr</u>	
Death	Injecto	n (Epinephrine) Auto or 0.3 Mg			S	Unknown	Unk			Myl	an
	Atorva				С		20 N	lg, Unk			
	Clopic				С		75 N	lg, Unk			
	Perino	lopril			С		2 Mg	g, Unk			
	Lyrica				С		300	Mg, Unk			
	Lyrica				С		150	Mg, Unk			
	Panto	orazole			С		40 N	lg, Unk			
	Vesica	are			С		10 M	lg, Unk			
	Lantus	3			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jan-2015	10717673	EXPEDITED (15-DAY)			LT	SE-MYLANI 2014M1000				Unknown	SWE
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mfr	
Device Failure; Drug Effect Incomplete	Epipe	า			S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jan-2015	10437499	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014M1002				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	g <u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Injury; Syncope	Epipe	n Auto-Injector			S	Intramuscular	0.3	Mg, Prn		Myl	an



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jan-2015	10654430	EXPEDITED (15-DAY)			HO, LT	US-MYLAN 2014M1013	_			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Wron Technique In Product Usage Process	-	n Auto-Injector phrine			S S	Intramuscular Intramuscular	0.3 Mg Unk	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Feb-2015	10677280	EXPEDITED (15-DAY)			LT	US-MYLAN 2014M1015	_			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Unresponsive To Stimi	uli Epipe	n Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Feb-2015	10779188	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2015M1002	_			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Unk		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Feb-2015	10779189	EXPEDITED (15-DAY)			LT	US-MYLAN 2015M1003				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug Ineffective	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Feb-2015	10785549	EXPEDITED (15-DAY)			DE	ZA-MYLAN 2015M1002				Unknown	ZAF
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	



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Expired Device Used	Epiper	n Auto-Injector			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Feb-2015	10785694	EXPEDITED (15-DAY)		0	Т	US-MYLANI 2015M1003	_			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure	Epiper	n Jr. Auto-Injector			S	Intramuscular	0.15 N	⁄lg, Prn		М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	Sex	Country
11-Feb-2015	10785777	EXPEDITED (15-DAY)		0	Т	US-MYLANI 2015M1002				Unknown	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>otc</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure 1	ັດ Fniner	1 AUIO-INIECIO!								IVI	ylan
Accidental Exposure To Product; Asthenia; Dyspnoea; Fatigue; Hyperhidrosis; Injection Site Discolouration; Injection Site Hypoaesthesia; Pyrexia Tremor	n	n Auto-Injector			S	Intramuscular	0.3 Mg	g, 1 111			
Product; Asthenia; Dyspnoea; Fatigue; Hyperhidrosis; Injectior Site Discolouration; Injection Site Hypoaesthesia; Pyrexia Tremor	n	Case Type	Health	Prof O	utcomes	Mfr Contro		503B Facility	Age	Sex	Country
Product; Asthenia; Dyspnoea; Fatigue; Hyperhidrosis; Injectior Site Discolouration; Injection Site Hypoaesthesia; Pyrexia Tremor	n a;	·	Health	Prof O	utcomes		<b>DI #</b> _ABS-		Age	<u>Sex</u> Unknown	<u>Country</u> AUS
Product; Asthenia; Dyspnoea; Fatigue; Hyperhidrosis; Injection Site Discolouration; Injection Site Hypoaesthesia; Pyrexis Tremor	n a; <u>Case #</u>	Case Type EXPEDITED (15-DAY)	Health Comp.		utcomes	Mfr Contro AU-MYLANI	<b>DI #</b> _ABS-	503B Facility	Age Duration		AUS
Product; Asthenia; Dyspnoea; Fatigue; Hyperhidrosis; Injectior Site Discolouration; Injection Site Hypoaesthesia; Pyrexia Tremor FDA Received Date 18-Feb-2015	n a; <u>Case #</u> 10815359 <u>Produ</u>	Case Type  EXPEDITED (15-DAY)  Ict  The second seco		Ľ	utcomes	Mfr Contro AU-MYLANI 2015M1004	<b>DI #</b> _ABS- 751	503B Facility	-	Unknown <u>Mf</u>	AUS
Product; Asthenia; Dyspnoea; Fatigue; Hyperhidrosis; Injectior Site Discolouration; Injection Site Hypoaesthesia; Pyrexis Tremor  FDA Received Date  18-Feb-2015  Preferred Term  Needle Issue; Skin Wound; Therapeutic Response Delayed; Wound	Case # 10815359  Produ	Case Type  EXPEDITED (15-DAY)  Ict  The second seco	Comp.	OTC	utcomes T Role	Mfr Contro AU-MYLANI 2015M1004	<b>DI #</b> _ABS- 751 	503B Facility	-	Unknown <u>Mf</u>	AUS <u>r</u>
Product; Asthenia; Dyspnoea; Fatigue; Hyperhidrosis; Injectior Site Discolouration; Injection Site Hypoaesthesia; Pyrexis Tremor  FDA Received Date  18-Feb-2015  Preferred Term  Needle Issue; Skin Wound; Therapeutic Response Delayed; Wound	a;  Case #  10815359  Produ  Epiper Injecto	Case Type EXPEDITED (15-DAY)  Ict  The Jr Adrenaline Auto-  Tr Adrenaline Auto-  Tr Adrenaline Auto-  Tr Adrenaline Auto-	Comp.	OTC  Prof O	utcomes T Role S	Mfr Contro AU-MYLANI 2015M1004 Route	DI #  _ABS751	503B Facility e Text Once	<u>Duration</u>	Unknown <u>Mf</u> M	AUS <u>r</u> ylan



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Device Failure; Drug Ineffective	Epipe	n Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		My	/lan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822279	NON-EXPEDITED				US-MYLAN 2014S1002				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipe	n Jr. Auto-Injector			S	Intramuscular	.15 M	lg,Prn		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822286	NON-EXPEDITED				US-MYLAN 2014S1000				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	Mfr	<u>:</u>
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822293	NON-EXPEDITED				US-MYLAN 2014S1000	_			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	[
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	.3 Mg	g,Prn		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822298	NON-EXPEDITED				US-MYLAN 2014S1003				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Injection Site Joint Pain		n Auto-Injector			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822303	NON-EXPEDITED				US-MYLAN 2014S1004			48 YR	Female	USA



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Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	
Device Failure	E	Epipen Auto-Injector			S	Intramuscular	.3 Mg,Prn		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Con	atrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	1082230	7 NON-EXPEDITED				US-MYLA 2014S10		14 YR	Female	USA
Preferred Term	<u>!</u>	Product	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mf</u>	
Gait Disturbance; Injective Reaction; Musculoskeletal Stiffne		Epipen Auto-Injector Epipen Auto-Injector			s s	Intramuscular	.3 Mg,Prn		•	/lan /lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Con	atrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	1082231	1 NON-EXPEDITED				US-MYLA 2014S10	=	58 YR	Male	USA
Preferred Term	!	Product	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mf</u>	<u>:</u>
Device Failure	E	Epipen Auto-Injector			S		Unk Unk,Prn		My	/lan
	F	Prednisone			С	Oral	5 Mg,Qd			
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	1082231	6 NON-EXPEDITED				US-MYLA 2014S10	=		Female	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mf	<u>-</u>
Accidental Exposure T Product	Γο Ε	Epipen Jr. Auto-Injector			S		Unk		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	1082232	0 NON-EXPEDITED				US-MYLA 2014S10	=		Female	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>-</u>
Accidental Exposure T Product	Γο Ε	Epipen Auto-Injector			S		Unk		My	/lan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822324	EXPEDITED (15-DAY)		H	O, OT	US-MYLANI 2014S10054	_			Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product	o Epiper	n Auto-Injector			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822329	NON-EXPEDITED				US-MYLANI 2014S10074	_			Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product	o Epiper	n Auto-Injector			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822333	NON-EXPEDITED				US-MYLANI 2014S10066			58 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Blood Pressu Increased; Dizziness; Heart Rate Increased		n Auto-Injector			S	Intramuscular	.3 Mg	,Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822339	NON-EXPEDITED				US-MYLANI 2014S10084	-			Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Heart Rate Increased	Epiper	n Auto-Injector			S	Intramuscular	Unk L	Jnk,Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822346	NON-EXPEDITED				US-MYLANI 2014S10059			60 YR	Male	USA



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Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Haemorrhage		en Auto-Injector			S		Unk		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015	10822354	NON-EXPEDITED				US-MYLAI 2014S101			Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	.3 Mg,Prn		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822361	NON-EXPEDITED				US-MYLAI 2014S101	_		Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Drug Administration E Unevaluable Event	rror; Epipe	en Auto-Injector			S		Unk		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822367	NON-EXPEDITED				US-MYLAI 2014S101			Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product	Γο Ερίρε	en Auto-Injector			S		Unk Unk,Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822376	NON-EXPEDITED				US-MYLAI 2014M100		33 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injury Associa With Device		en Auto-Injector			S		Unk Unk		Му	rlan



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FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822381	NON-EXPEDITED				US-MYLAN 2014S1017	_			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822384	NON-EXPEDITED				US-MYLAN 2014S1012	_			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Haemorrhage		n Auto-Injector			S		Unk	Unk,Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822389	NON-EXPEDITED				US-MYLAN 2014S1000				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822391	NON-EXPEDITED				US-MYLAN 2014S1002			8 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	n Jr. Auto-Injector			S	Intramuscular	.15 N	/lg,Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822392	NON-EXPEDITED				US-MYLAN 2014S1004				Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosa	ge Text	Duration	Mfr	

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Accidental Exposure To Product	o Epipe	n Auto-Injector			S		Unk			N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822394	NON-EXPEDITED				US-MYLAN 2014S1002				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Wrong Technique In Product Usage Process		n Auto-Injector			S		Unk			N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015	10822395	NON-EXPEDITED				US-MYLAN 2014S1002			61 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Device Failure; Injection	Poin				S	Intramuscular	.3 Mg,F	Prn		N	/lylan
Site Pain	Clarit	in /00917501/			С		Unk				
	Potas	sium			С		Unk				
	Ceftir	1/00454603/			С		250 Mg	j,Unk			
	Blood	l Pressure Pill			С		Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u> Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822398	NON-EXPEDITED				US-MYLAN 2014S1003				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Gait Disturbance; Inject	tion Epipe	n Auto-Injector			S	Intramuscular	.3 Mg,F	Prn		N	/lylan
Site Bruising; Muscle Haemorrhage	Bene	fix			С		Unk Ur	nk,3xw			
aomernage	Bena	dryl			С		Unk Ur	nk,3xw			
	Нера	rin Lock Flush			С		Unk Ur	ık,3xw			
	Finas	teride			С		Unk				
	Clona	azepam			С		Unk				
	Mirta	zapine			С		Unk				

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822400	NON-EXPEDITED				US-MYLA 2014M10	-		53 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Burning Sensation; Ga Disturbance	ait Epipe	n Auto-Injector			S		Unk,	Prn		M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822403	NON-EXPEDITED				US-MYLA 2014S100				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Injection Site Injury; Injection Site Pa		n Auto-Injector			S		Unk			M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822405	NON-EXPEDITED				US-MYLA 2014S100	-			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>otc</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Intentional Product Misuse; Unevaluable Event	ō Epipe	n Auto-Injector			S		.6 Mg	I,Once		M	lylan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822406	NON-EXPEDITED				US-MYLA 2014S100	_			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Unevaluable Event	o Epipe	n Auto-Injector			S		Unk			M	lylan



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<b>FDA Received Date</b>	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822407	NON-EXPEDITED				US-MYLAN 2014S1006	_		15 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Injection Site Pain	Epipe Bena	en Auto-Injector dryl			S C	Intramuscular Oral	.3 Mg Unk	,Prn		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822408	NON-EXPEDITED				US-MYLAN 2014M1000	_			Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure Product; Expired Product Administered		en Auto-Injector			S					M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822409	NON-EXPEDITED				US-MYLAN 2014S1004				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure 7 Product; Injection Site Hypoaesthesia; Injecti Site Swelling	,	en Auto-Injector			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822410	NON-EXPEDITED				US-MYLAN 2014S1004			6 YR	Male	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure 7 Product By Child; Inje Site Pain		en Auto-Injector			S		Unk			M	ylan



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FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822411	NON-EXPEDITED				US-MYLAN 2014S1001				Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product; Injection Site Swelling; Peripheral Swelling	o Epipe	n Auto-Injector			S		Unk			N	<b>l</b> ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822412	NON-EXPEDITED				US-MYLAN 2014M100	-		59 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Defective	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		N	1ylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822413	NON-EXPEDITED				US-MYLAN 2014S1003				Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	.3 Mg	,Prn		N	1ylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822414	EXPEDITED (15-DAY)		•	ОТ	US-MYLAN 2014S1004	-			Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Anaphylactic Reaction;	; Epipe	n Auto-Injector			S	Subcutaneous	.3 Mg	,Prn		N	lylan
Drug Ineffective	Benef	ix			С		-	Jnk,3xw			
	Benad	dryl			С		Unk L	Jnk,3xw			
	Hepar	in Lock Flush			С		Unk L	Jnk,3xw			
	Finast	teride			С		Unk				



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						Dotalioa i	•				
	Clonaz	repam			С		Unk				
	Mirtaza	apine			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822415	NON-EXPEDITED				US-MYLAN 2014S1002				Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epiper	Auto-Injector			S	Intramuscular	.3 Mg,	Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822416	NON-EXPEDITED				US-MYLAN 2014M1000				Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
ccidental Exposure To Epipen Auto-Injector roduct By Child; Heart ate Increased				S					Му	lan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822417	EXPEDITED (15-DAY)		(	ОТ	US-MYLAN 2014S1004	_			Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product	Γο Epiper	Jr. Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822419	NON-EXPEDITED				US-MYLAN 2013S1029	_			Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epiper	Auto-Injector			S	Intramuscular	Unk			Му	lan
	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	Age	Sex	Country
FDA Received Date	Case #	<u>case rype</u>	Hount	<u></u>							

Note: If the field is blank, there is no data.

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Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	<u>ige Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product	o Epipe	en Auto-Injector			S		Unk			N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822421	NON-EXPEDITED				US-MYLA 2014S10			57 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	<u>ige Text</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>
Paraesthesia; Tremor	Epipe	en Auto-Injector			S		Unk	Unk,Once		N	/lylan
	Bena	dryl			S		Unk	Unk,Once			
FDA Received Date	Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facil		503B Facility	<u>Age</u>	<u>Sex</u>	Country					
18-Feb-2015	10822422	EXPEDITED (15-DAY)			ОТ		US-MYLANLABS- 2014S1005783			Female USA	
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	<u>ige Text</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product; Ventricular Extrasystoles	/entricular				S		Unk	Unk,Once		N	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822423	NON-EXPEDITED				US-MYLA 2014S10				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	<u>ige Text</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>
Feeling Jittery; Somnolence	Epipe Bena	en Auto-Injector dryl			S S		Unk			N	<b>l</b> ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822425	NON-EXPEDITED				US-MYLA 2014S10				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	<u>ige Text</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>
Injection Site Pain; Injection Site Scar;	Epipe	en Auto-Injector			S		Unk			N	/lylan



Product Administered At

Inappropriate Site											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822427	NON-EXPEDITED				US-MYLA 2014S100	-			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	:
Device Failure	Epipe	n Jr. Auto-Injector			S	Intramuscular	.15 M	lg,Prn		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822428	NON-EXPEDITED				US-MYLA 2014S100			51 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	:
Wrong Technique In Product Usage Proces	Rispe Synth				S C C	Intramuscular Oral Oral	.3 Mg Unk Unk Unk	ı,Prn		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Con	trol #	503B Facility	Age	<u>Sex</u>	Country
18-Feb-2015	10822429	NON-EXPEDITED				US-MYLA 2014S100	-			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822430	NON-EXPEDITED				US-MYLA 2014S100				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Injection Site Oedema		en Auto-Injector			S		Unk			My	/lan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015	10822432	NON-EXPEDITED				US-MYLA 2014S100				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk l	Jnk,Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822433	NON-EXPEDITED				US-MYLA 2014S100			70 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	<u>r</u>
Fatigue; Injection Site	Epipe	n Auto-Injector			S	Intramuscular	.3 Mg	g,Prn		M	ylan
Pain; Nervousness	Solu-l	Medrol			S	Intravenous (no otherwise speci					
	Predr			S	Oral	Unk					
	Lantu	S			С	Subcutaneous	Unk				
	Novolog				С	Subcutaneous	Unk				
	Keppra				С	Oral	Unk				
	Metfo	rmin			С	Oral	Unk				
	Lipito	ſ			С	Oral	Unk				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822434	NON-EXPEDITED				US-MYLA 2014S100				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822435	NON-EXPEDITED				US-MYLA 2014S100				Male	USA



Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>kt</u>	<b>Duration</b>	<u>Mf</u> ı	<u>r</u>
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk			My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ontrol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822436	NON-EXPEDITED					LANLABS- 1016859			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Tex	<u>kt</u>	<u>Duration</u>	<u>Mf</u>	<u>t</u>
Drug Administration Er No Adverse Event	rror; Epipe	n Auto-Injector			S		Unk			My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ontrol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822437	NON-EXPEDITED					LANLABS- 1007539			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>kt</u>	<u>Duration</u>	<u>Mf</u>	<u>.</u>
Accidental Exposure T		n Auto-Injector	S .3 Mg,Prn						My	ylan	
Product; Exposure Dui Pregnancy; Unevaluab	, ⊏bibe	n Auto-Injector n Auto-Injector			S S						ylan ylan
Event	Benad				C		Unk			IVI	ylaii
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ontrol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822438	NON-EXPEDITED					LANLABS- 1003438			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Tex	<u>kt</u>	<u>Duration</u>	Mf	
Drug Administration Er	rror Epipe	n Auto-Injector			S		Unk Unk,C	nce		My	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ontrol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822440	NON-EXPEDITED					LANLABS- 1008559			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Tex	<u>xt</u>	<u>Duration</u>	<u>Mf</u>	<u>.</u>
Pain	Epipe	n Auto-Injector			S		Unk			M	ylan

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FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822441	NON-EXPEDITED				US-MYLA 2014M10			53 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Anxiety; Expir Product Administered		Auto-Injector s Vaccin			S C		Unk Unk	Unk, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822445	NON-EXPEDITED				US-MYLA 2014S100	_		13 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Hypoaesthesi Swelling		Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822446	EXPEDITED (15-DAY)		(	ОТ	US-MYLA 2014S100			10 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product By Child	o Epipen	Jr. Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822447	NON-EXPEDITED				US-MYLA 2014M10	_			Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Injection Site Discolouration	o Epipen	Auto-Injector			S		Unk	Unk, Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822451	NON-EXPEDITED				US-MYLA 2014S100				Female	USA

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# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	en Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015	10822453	NON-EXPEDITED				US-MYLA 2014M100	-		23 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Incorrect Dose	Epipe	en Auto-Injector			S		Unk, (	Once		M	ylan
Administered; Wrong Technique In Product Usage Process		en Auto-Injector en Auto-Injector c			S S C						ylan ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10822454	NON-EXPEDITED				US-MYLA 2014S100			49 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Expired Product Administered; Injection Site Pain; Nervousness	uct	en Auto-Injector			S	Intramuscular	.15 M	g,Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822457	NON-EXPEDITED				US-MYLA 2014S100				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Nervousness	o Epipe	en Auto-Injector	njector S Unk				M	ylan			
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015	10822459	NON-EXPEDITED				US-MYLA 2014S100				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>



#### **FDA Adverse Event Reporting System** Freedom of Information Act (FOIA) **Detailed Report**

Circumstance Or

S Epipen Auto-Injector .3 Ma.Prn Mylan

Information Capable C Leading To Medication Error; Injection Site Pa	Of n	an Auto-injector					.3 Mg,	FIII		iviy	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822460	NON-EXPEDITED				US-MYLAN 2014S1011	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	.3 Mg,	Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822461	NON-EXPEDITED				US-MYLAN 2014S1009				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Hypoaesthes		en Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822462	NON-EXPEDITED				US-MYLAN 2014S1010	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Effect Incomplete Swelling Face	e; Epipe	en Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822465	NON-EXPEDITED				US-MYLAN 2014S1009			3 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	en Jr. Auto-Injector			S	Intramuscular	.15 Mg	g,Prn		Му	lan
		en Jr. Auto-Injector en Jr. Auto-Injector			S S					My My	
	Bena				C		Unk			iviy	iuii



							•				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822466	NON-EXPEDITED				US-MYLAN 2014S1000	-			Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
njection Site Injury	Epipe	n Jr. Auto-Injector			S	Intramuscular	.15 Mg	g,Prn		М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822468	NON-EXPEDITED				US-MYLAN 2014S1007				Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
njection Site Pain	Epipe	n Auto-Injector			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822469	NON-EXPEDITED				US-MYLAN 2014M1014			44 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Devidust; Expired Devidus Used; Injection Site Pa	ce	n Auto-Injector			S	Subcutaneous	0.3 Mg	g, Once		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822471	NON-EXPEDITED				US-MYLAN 2014S1004				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product	Го Еріре	n Auto-Injector			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	10822472	NON-EXPEDITED				US-MYLAN			7 YR	Male	USA
18-Feb-2015	10022472					2014S1012	232				

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<b>D</b> · <b>D</b> · ·										
Device Failure	Epipe	n Jr. Auto-Injector			S	Intramuscular	.15 Mg,Prn		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015	10822473	NON-EXPEDITED				US-MYLANL 2014S10098			Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product	o Epipe	n Auto-Injector			S		Unk		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822475	NON-EXPEDITED				US-MYLANL 2014S10108	=		Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Expired Produ Administered; Hypoaesthesia; Periphe Coldness; Poor Periphe	uct eral	n Auto-Injector			S		Unk		,	rlan
	erai									
Circulation	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol# 503B Facility	Age	<u>Sex</u>	Country
Circulation  FDA Received Date		Case Type  NON-EXPEDITED	<u>Health</u>	Prof C	Outcomes	Mfr Contro US-MYLANL 2014S10088	ABS-	Age 52 YR	<u>Sex</u> Female	<b>Country</b> USA
Circulation  FDA Received Date  18-Feb-2015	Case #	NON-EXPEDITED	Health Comp.	Prof C	Outcomes Role	US-MYLANL	ABS-			USA
Circulation  FDA Received Date  18-Feb-2015  Preferred Term	Case # 10822476 Produ	NON-EXPEDITED				US-MYLANL 2014S10088	ABS- 27	52 YR	Female Mfr	USA
Circulation  FDA Received Date  18-Feb-2015  Preferred Term  Device Failure	Case # 10822476 Produ	NON-EXPEDITED	Comp.	OTC	Role	US-MYLANL 2014S10088 Route	ABS- 27 Dosage Text .3 Mg,Prn	52 YR	Female Mfr	USA
Circulation  FDA Received Date  18-Feb-2015  Preferred Term  Device Failure  FDA Received Date	Case # 10822476  Produ	NON-EXPEDITED  uct  n Auto-Injector	Comp.	OTC	Role S	US-MYLANL 2014S10088 Route Intramuscular	Dosage Text  .3 Mg,Prn  .1 # 503B Facility  ABS-	52 YR <u>Duration</u>	Female <u>Mfr</u> My	USA : /lan
Circulation  FDA Received Date  18-Feb-2015  Preferred Term  Device Failure  FDA Received Date	Case #  10822476  Produ  Epiper	NON-EXPEDITED  LCT  In Auto-Injector  Case Type  NON-EXPEDITED	Comp.	OTC	Role S	US-MYLANL 2014S10088  Route  Intramuscular  Mfr Contro	Dosage Text  .3 Mg,Prn  .1 # 503B Facility  ABS-	52 YR  Duration  Age	Female  Mfr  My  Sex	USA vlan Country USA
Circulation  FDA Received Date  18-Feb-2015  Preferred Term  Device Failure  FDA Received Date  18-Feb-2015	Case #  10822476  Produ Epipel  Case #  10822477  Produ	NON-EXPEDITED  LCT  In Auto-Injector  Case Type  NON-EXPEDITED	Comp.  Health	OTC Prof C	Role S Outcomes	US-MYLANL 2014S10088  Route  Intramuscular  Mfr Contro  US-MYLANL 2014S10116	Dosage Text  .3 Mg,Prn  st# 503B Facility  ABS- 00	52 YR  Duration  Age 7 YR	Female  Mfr My  Sex  Male	USA vlan Country USA

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015	10822478	NON-EXPEDITED				US-MYLAN 2014S1011				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	Mfr	
Nausea	Epipe	n Auto-Injector			S	Intramuscular	.3 M	g,Prn		Му	/lan
	Nexiu	ım			С		Unk				
	Levot	hyroxine			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822480	NON-EXPEDITED				US-MYLAN 2014S1014	_			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mfr	:
njection Site Bruising	Epipe	n Auto-Injector			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822481	NON-EXPEDITED				US-MYLAN 2014S1015				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk	Unk,Once		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822482	NON-EXPEDITED				US-MYLAN 2014S1010	_			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	:
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		.3 M	g,Once		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	<u>rol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822485	NON-EXPEDITED				US-MYLAN 2014M1003				Female	USA



Preferred Term	Prod	luct	Comp. OTC Role Route Dosage Text		<u>Duration</u>	Mf	<u>r</u>					
Device Failure; Malais	se Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		M	ylan		
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol # 503B Fac	ility Age	<u>Sex</u>	Country		
18-Feb-2015	10822486	NON-EXPEDITED				US-MYLAN 2014M1002		4 YR	Male	USA		
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mf	<u>r</u>		
Accidental Exposure T Product By Child; Injec Site Injury; Palpitations Somnolence	ction	en Jr. Auto-Injector			S		Unk, Prn		M	ylan		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Fac	ility <u>Age</u>	<u>Sex</u>	Country		
18-Feb-2015	10822487	NON-EXPEDITED				US-MYLAN 2014S1012			Male	USA		
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mf	<u>r</u>		
Accidental Exposure T Product	Го Еріре	en Auto-Injector			S		Unk Unk,Once		M	ylan		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Fac	ility Age	<u>Sex</u>	Country		
18-Feb-2015	10822488	NON-EXPEDITED				US-MYLAN 2014S1009			Male	USA		
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mf	<u>r</u>		
Injection Site Haemorrhage	Epipe	en Auto-Injector			S		Unk		M	ylan		
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol # 503B Fac	ility Age	<u>Sex</u>	Country		
18-Feb-2015	10822489	NON-EXPEDITED				US-MYLAN 2014S1015	_		Female	USA		
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mf	<u>r</u>		
Drug Ineffective; Glossodynia; Tremor	Epipe	en Auto-Injector			S	Intramuscular	.3 Mg,Prn		M	ylan		

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822491	NON-EXPEDITED				US-MYLAN 2014S1015				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Expired Produ Administered		n Jr. Auto-Injector			S	Intramuscular	.15 Mg	,,Once		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822492	NON-EXPEDITED				US-MYLAN 2014S1013				Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure Te Product; Muscle Twitch		n Auto-Injector			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822493	NON-EXPEDITED				US-MYLAN 2014S1009	_			Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Rash Generalised	Epipe	n Jr. Auto-Injector			S	Intramuscular	.15 Mg	ı,Prn		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822499	NON-EXPEDITED				US-MYLAN 2014S1016	_			Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product	o Epipe	n Auto-Injector			S		Unk U	nk,Once		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822501	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2014M1003			31 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	



Anaphylactic Reaction;	Epiper	n Auto-Injector			S	Intramuscular	Unk			My	ylan
Orug Ineffective	Epiper Motrin	n Auto-Injector	S C		Unk			My	ylan		
	Benad	ryl /00000402/			С						
FDA Received Date C	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015 1	0822502	NON-EXPEDITED				US-MYLANI 2014S10154				Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	<u>.</u>
Accidental Exposure To Product	Epiper	n Auto-Injector			S		Unk			My	ylan
FDA Received Date C	case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015 1	0822504	NON-EXPEDITED				US-MYLANI 2014S10163	_		34 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	<u>r</u>
Accidental Exposure To Product; Injection Site Bruising; Injection Site Pain; Injection Site Swelling	Epiper	n Jr. Auto-Injector			S		.15 M	g,Once		Му	ylan
FDA Received Date C	case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015 1	0822507	NON-EXPEDITED				US-MYLANI 2014M1003			20 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	1
Accidental Exposure To Product; Injection Site Injury	Epiper	n Jr. Auto-Injector			S		Unk U	Ink, Once		My	ylan
FDA Received Date C	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015 1	0822511	NON-EXPEDITED				US-MYLANI 2014M1001			21 YR	Female	USA
				ОТС	Role						



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Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 N	Mg, Prn	Mylan		
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822512	NON-EXPEDITED				US-MYLANL 2014S10141	-		5 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product By Child; Expi Product Administered		n Jr. Auto-Injector			S		Unk	Unk,Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822514	NON-EXPEDITED				US-MYLANL 2014S10160			2 YR	Male	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product By Child	o Epipe	n Auto-Injector			S		Unk	Unk,Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822518	NON-EXPEDITED				US-MYLANL 2014M10067	-		74 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	Mf	<u>r</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 N	Mg, Prn		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822521	EXPEDITED (15-DAY)		(	TC	US-MYLANL 2014S10165				Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	Mf	<u>r</u>
Cardiac Flutter	Epipe	n Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822522	NON-EXPEDITED				US-MYLANL 2014M10090				Female	USA



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<u>Preferred Term</u>	<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product; Injection Site Haemorrhage; Injury Associated With Device	oduct; Injection Site emorrhage; Injury				S		0.3 Mg, U	nk		N	1ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Feb-2015	10822524	NON-EXPEDITED				US-MYLAN 2014M1005			63 YR	Female	USA
Preferred Term			Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, P	rn		N	1ylan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol # <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822525	EXPEDITED (15-DAY)		(	OT	US-MYLAN 2014M1009			47 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Drug Ineffective; Dyspnoea; Wheezing	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, P	rn		N	1ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822526	NON-EXPEDITED				US-MYLAN 2014S1011			48 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Drug Ineffective; Swel	ling Epipe	en Auto-Injector			S	Intramuscular	.3 Mg,Prn			N	<b>1</b> ylan
Face	Epipe Epipe	en Auto-Injector en Auto-Injector en Auto-Injector			S S S					N	1ylan 1ylan 1ylan
	Lactu				С		Unk				
	Aspir				С		81 Mg,Un	k			
	•	ocodone 			С		Unk				
	Amlo	dipine			С		10 Mg,Un	k			



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FDA Received Date	Case #	Case Type	Health	Prof O	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822527	NON-EXPEDITED				US-MYLA 2014M10	-		76 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Drug Effect Decreased Injection Site Pain; Swollen Tongue	d; Epipe	n Auto-Injector			S		Unk,	Prn		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>Dutcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822529	NON-EXPEDITED				US-MYLA 2014S10				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	g <u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Device Malfunction	Epipe	n Auto-Injector			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822532	NON-EXPEDITED				US-MYLA 2014S10	-			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	g <u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Drug Prescribing Error	r Epipe	n Auto-Injector			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	<u>Dutcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822533	NON-EXPEDITED				US-MYLA 2014S10			41 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Palpitations	Epipe	n Auto-Injector			S		Unk	Unk,Once		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822534	NON-EXPEDITED				US-MYLA 2014M10	-		28 YR	Male	USA
Preferred Term	Produ	uot	Comp.	отс	Role	Route	Dosa	ge Text	Duration	Mf	



Device Failure; Drug Ineffective; Rash	Epipe			S		Unk,	Prn		Му	rlan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822538	EXPEDITED (15-DAY)		C	DΤ	US-MYLAN 2014M1003			5 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Anxi		n Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822539	NON-EXPEDITED				US-MYLAN 2014S1016	_			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Administration Er No Adverse Event	ror; Epipe	n Auto-Injector	S Unk					Mylan			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822543	NON-EXPEDITED				US-MYLAN 2014S1016	-			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Administration Er No Adverse Event	ror; Epipe	n Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822545	EXPEDITED (15-DAY)		C	T	US-MYLAN 2014M1006			52 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction	; Epipe	n Auto-Injector			S		Unk			Му	lan
Drug Ineffective	Klono	pin			С		Unk				
	Vistar	il /00058402/			С		Unk				



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822546	NON-EXPEDITED				US-MYL 2014M1	ANLABS- 000094		43 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mf	<u>.</u>
Drug Effect Decreased	d; Epipe	n Jr. Auto-Injector			S		Unk			M	ylan
Expired Product Administered; Intentior Product Misuse	nai Epipe Predn	n Jr. Auto-Injector n Jr. Auto-Injector isone d Antibacterials			S S C C						ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822548	NON-EXPEDITED				US-MYL 2014S1	ANLABS- 015600			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered		n Auto-Injector			S		Unk l	Jnk,Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822553	NON-EXPEDITED				US-MYL 2014S1	ANLABS- 014523		10 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mf	<u>.</u>
Accidental Exposure T	o Epipe	n Auto-Injector			S		.3 Mg	,Once		M	ylan
Product By Child; No Adverse Event	Albute	erol			С		Unk				
TOVOISE LYGIIL	Zyrted	;			С		Unk				
	Epipe	n			С		Unk				
	Flona	se /00972202/			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822554	NON-EXPEDITED				US-MYLANLABS- 2014M1003006				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mf	

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							- 1				
Heart Rate Increased	Epipe	n Auto-Injector			S	Intramuscular	0.3 MI, Pr	rn		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>1 #</u>	03B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2015	10822556	NON-EXPEDITED				US-MYLANL 2014S10156				Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk Unk,	Once		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>1 #</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822558	NON-EXPEDITED				US-MYLANL 2014M10018			5 YR	Unknown	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child	o Epipe	n Jr. Auto-Injector			S		0.15 Mg,	Total		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>1 #</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822559	NON-EXPEDITED				US-MYLANL 2014M10087	-		19 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	Mfr	
Expired Product	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, C	Once		Му	⁄lan
Administered	Oral C	Contraceptive Nos			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>1 # 5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822560	NON-EXPEDITED				US-MYLANL 2014S10170	-			Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Swelling Face	Epipe	n Auto-Injector			S		Unk			Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	I # <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822561	NON-EXPEDITED				US-MYLANL 2014S10158	-			Female	USA



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Dura</u>	ation	Mfr
Accidental Exposure T Product; Expired Prod Administered		n Auto-Injector			S		Unk			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B	B Facility Age	<u>Sex</u>	Country
18-Feb-2015	10822563	NON-EXPEDITED				US-MYLAN 2014M1009		72 Y	'R Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Dura</u>	ation .	<u>Mfr</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B	B Facility Age	<u>Sex</u>	Country
18-Feb-2015	10822568	NON-EXPEDITED				US-MYLAN 2014M1000		29 Y	'R Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Dura</u>	ation .	<u>Mfr</u>
Accidental Exposure T Product; Expired Prod Administered; Injectior Site Pain; Tremor	uct	n Auto-Injector			S		0.3 Mg, Once	9		Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol # 503B	B Facility Age	<u>Sex</u>	Country
18-Feb-2015	10822569	NON-EXPEDITED				US-MYLAN 2014S1014	-		Male	USA
Preferred Term	<u>Prod</u>	uct	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Dura</u>	ation .	<u>Mfr</u>
Dizziness; Heart Rate Irregular; Vomiting	Epipe	n Auto-Injector			S		Unk Unk,Prn			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B	B Facility Age	<u>Sex</u>	Country
18-Feb-2015	10822571	NON-EXPEDITED				US-MYLAN 2014M1013		42 Y	'R Female	e USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	<b>Dosage Text</b>	<u>Dura</u>	ation	<u>Mfr</u>
	<u></u>									



FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822572	NON-EXPEDITED				US-MYL 2014S10	ANLABS- 015696		7 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	n Jr. Auto-Injector			S		Unk	Unk,Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822575	NON-EXPEDITED				US-MYL 2014M1	ANLABS- 009166			Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mf	<u>r</u>
Drug Administration En Incorrect Dose Administered; Oxygen Saturation Decreased; Upper Respiratory Tra Inflammation		n			S		Unk	Unk, Prn		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822576	NON-EXPEDITED				US-MYL 2014M1	ANLABS- 000384		14 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product	o Epipe	n Auto-Injector			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822578	NON-EXPEDITED				US-MYL 2014M1	ANLABS- 004239			Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Expired Product; Administered; Pain In Extremity; Skin Discolouration		n Auto-Injector			S		0.3 N	∕lg, Prn		M	ylan

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822586	NON-EXPEDITED				US-MYLANL 2014M10109				Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product	o Epi	pen Auto-Injector			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822588	NON-EXPEDITED				US-MYLANI 2014S10169			4 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	Mfr	:
Accidental Exposure T Product By Child	o Epi	pen Auto-Injector			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822592	EXPEDITED (15-DAY)		0	Т	US-MYLANI 2014M10059	-		22 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product	o Epi	pen Auto-Injector			S		Unk U	Ink, Once		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822599	NON-EXPEDITED				US-MYLANL 2014M1014			5 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product By Child; Injec Site Erythema		pen Jr. Auto-Injector			S	Intramuscular	0.15 N	Mg, Once		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	40000004	NON-EXPEDITED				US-MYLANL	_			Female	USA
18-Feb-2015	10822601	NON EXILEDITED				2014M1013	773				

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Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822632	NON-EXPEDITED				US-MYLANL 2014M10135			36 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10822638	NON-EXPEDITED				US-MYLANL 2014M10096				Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Needle Issue	e Epipen	Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2015	10855539	DIRECT			ОТ				35 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Dr Ineffective; Feeling Ho Malaise					S		Giver	n Into/Under The Sk	in	Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Feb-2015	10857898	EXPEDITED (15-DAY)			DE, OT	GB-MYLANL 2015M10048				Unknown	GBR
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective; Statu Asthmaticus	s Epipen	Auto-Injector 0.3 Mg			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Feb-2015	10858241	EXPEDITED (15-DAY)			LT	US-MYLANL 2015M10041				Unknown	USA

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Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage 1	<u> Fext</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Feb-2015	10633457	EXPEDITED (15-DAY)		L	T, OT	US-MYLAI 2014M101				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Fext</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Expir Product Administered	ed Epiper	Auto-Injector			S	Unknown	Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Feb-2015	10872033	EXPEDITED (15-DAY)		0	Т	SE-MYLAI 2015M100				Unknown	SWE
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Fext</u>	<u>Duration</u>	Mfr	
Device Failure	Epiper	<u> </u>			S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2015	10611841	EXPEDITED (15-DAY)		Н	O, OT	GB-MYLA 2014M101				Unknown	GBR
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Fext</u>	<u>Duration</u>	Mfr	
Anaphylactic Shock; D		Auto-Injector 0.3 Mg			S		1 Df, 5x	d		Myl	an
Ineffective; Generalise Erythema; Hypotensio	n; Epipeii	Auto-Injector 0.3 Mg			S S					Myl	an
Pruritus; Pyrexia; Tren	nor	ne Linctus			S		Unk Unk				
	Difflam Cande Cyano Ezetim Insulat Istin Lopera	sartan cobalamin ibe ard /00646002/ mide : /00550802/			000000000		OHK				

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	Atorva	Atorvastatin Gaviscon /00237601/			С		Unk				
	Gaviso Insulin				C C						
FDA Received Date	Case #	Case Type	Health	Prof Ou		Mfr Contro	ol #	503B Facility	Age	Sex	Country
27-Feb-2015	10874610	EXPEDITED (15-DAY)	- I Gartin	0		GB-MYLAN 2015M1005	LABS-	<u>5552 . us</u>	<u>ge</u>	Unknown	GBR
<u>Preferred Term</u>	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	:
Device Failure; No Adverse Event	Epiper	n Auto-Injector 0.3 Mg			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Mar-2015	10877881	EXPEDITED (15-DAY)		0	Γ	FI-MYLANL 2015M1006				Unknown	FIN
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; No Adverse Event	Epiper	n Jr			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Mar-2015	10888284	EXPEDITED (15-DAY)		0	Г	US-MYLAN 2015M1005				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	•
Device Failure; Injectio Site Laceration	on Epiper	n Jr. Auto-Injector			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Mar-2015	10896040	EXPEDITED (15-DAY)		0	Γ	JP-MYLANL 2015M1002				Unknown	JPN
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Iliotibial Band Syndrom Injection Site Pain	Epiper	า			S S	Intramuscular	0.3 Mg	g, Unk		My	/lan /lan
	Epiper	า			S S					My	/lan



		Clarityn /00917501/			S						
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Mar-2015	109031	17 EXPEDITED (15-DA	AY)		HO, OT	GB-AURO APL-2015	OBINDO-AUR- 5-01891		69 YR	Female	GBR
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mf	<u>r</u>
Anaphylactic Shock; D		Amoxicillin			S	Unknown	Unk			Αι	ırobindo
Ineffective; Generalise Erythema; Heart Rate		Codeine Linctus			S	Unknown	Unk				
Irregular; Hypotension	;	Epipen			S	Unknown					
Pruritus; Pyrexia; Tren	nor	Atorvastatin			С	Unknown	Unk				
		Candesartan			С	Unknown	Unk				
		Cyanocobalamin			С	Unknown	Unk				
		Difflam			С	Unknown	Unk				
		Ezetimibe			С	Unknown	Unk				
		Gaviscon /00237601/			С	Unknown	Unk				
		Insulatard /00646002/			С	Unknown	Unk				
		Insulin			С	Unknown	Unk				
		Istin			С	Unknown	Unk				
		Loperamide			С	Unknown	Unk				
		Paracetamol			С	Unknown	Unk				
		Acidex			С	Unknown	Unk				
		Peptac /01521901/			С	Unknown	Unk				
		B12 /00056201/			С	Unknown	Unk, M	lonthly			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Mar-2015	109033	52 EXPEDITED (15-DA	AY)		HO, OT	PHHY201	4GB169469		69 YR	Female	GBR
Preferred Term		Product	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mf</u>	ŗ
Anaphylactic Shock; D		Codeine Phosphate			S	Unknown					
Ineffective; Generalise Erythema; Hypotensio		Amoxicillin			S	Unknown				No	ovartis

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Pruritus; Pyrexia; Tremor	Epipen			S	Unknown	1 Df, 5qd			
	Difflam			С	Unknown				
	Candesartan			С	Unknown				
	Cyanocobalamin			С	Unknown				
	Ezetimibe			С	Unknown				
	Insulatard			С	Unknown				
	Istin			С	Unknown				
	Acidex			С	Unknown				
	Loperamide			С	Unknown				
	Paracetamol			С	Unknown				
	Peptac			С	Unknown				
	Atorvastatin			С	Unknown				
	Gaviscon /01279101/			С	Unknown				
	Insulin			С	Unknown				
FDA Received Date Cas	e # Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Mar-2015 109	15747 EXPEDITED (15-DAY	)	I	HO, OT	GB-RANB 94175	AXY-2015RR-		Unknown	GBR
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Drug	Amoxicillin			S	Unknown	Unk		Rai	nbaxy
neffective; Generalised Erythema; Hypotension;	Codeine Linctus			S	Unknown	Unk			
Pruritus; Pyrexia; Tremor	Epipen			S	Unknown	1 Df 5 Times A Day, Solution For Injection In Pre-Filled Pen			
	Atorvastatin			С	Unknown	Unk			
	Candesartan			С	Unknown	Unk			
	Cyanocobalamin			С	Unknown	Unk			
	Difflam			С	Unknown	Unk			
	Ezetimibe			С	Unknown	Unk			
	Gaviscon			С	Unknown	Unk			



						Dotano	a itopoit				
	Insula	atard			С	Unknown	Unk				
	Insuli	in			С	Unknown	Unk				
	Istin				С	Unknown	Unk				
	Lope	ramide			С	Unknown	Unk				
	Parad	cetamol			С	Unknown	Unk				
	Acide	ex .			С	Unknown	Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Mar-2015	10969877	EXPEDITED (15-DAY)			НО	AU-MYL 2015M1	ANLABS- 008881			Unknown	AUS
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mfr	
Wrong Technique In Product Usage Proces		en Jr Adrenaline Auto- tor			S	Unknown				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Apr-2015	10973741	EXPEDITED (15-DAY)			ОТ	US-MYL 2015M1	ANLABS- 009652			Unknown	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Apr-2015	9559979	NON-EXPEDITED				US-PFIZ 2013275	ZER INC- 5228		57 YR	Female	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;		t			S		Unk			Pfiz	zer
Injection Site Swelling; Pyrexia; Rash	Epipe	en			S		Unk			Pfiz	zer
. j.ona, raon	Zofra	ın			S		Unk				
	Vitam	nin B			S		Unk				
	Tetar	nus Vaccine			S		Unk				



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Apr-2015	11058469	EXPEDITED (15-DAY)		С	T	GB-MYLAN 2015M1013				Unknown	GBR
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Expired Device Used		Auto-Injector 0.3 Mg			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-May-2015	11032954	EXPEDITED (15-DAY)		Ľ	Т	NZ-MYLANI 2015M1010	-			Unknown	NZL
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen				S		300 M	lg, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-May-2015	11051528	EXPEDITED (15-DAY)		C	T	US-MYLAN 2015M1011	_			Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S		0.3 M	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-May-2015	11073602	EXPEDITED (15-DAY)		С	T	JP-MYLANL 2015M1013	-			Unknown	JPN
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Injection Site Injury; Inj Associated With Device					S	Intramuscular	Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-May-2015	11101519	EXPEDITED (15-DAY)		С	T	US-MYLAN 2015M1011				Unknown	USA



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Myocardial Infarction	Epipe	n Auto-Injector	S 0.3 Mg, Unk				lg, Unk		Му	lan	
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-May-2015	10822497	EXPEDITED (15-DAY)		H	HO, OT	US-MYLAN 2014M1001	_			Unknown	USA
Preferred Term	<u>Prod</u> ı	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>le Text</u>	<b>Duration</b>	<u>Mfr</u>	
Heart Rate Increased; Injection Site Coldness Injection Site Discolouration; Injectic Site Hypoaesthesia; Injection Site Injury; Paraesthesia; Vasoconstriction; Wrot Technique In Product Usage Process	s; on ain;	n Auto-Injector			S	Intramuscular	0.3 M	lg, Prn		Му	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2015	11120250	EXPEDITED (15-DAY)		C	DΤ	US-MYLAN 2015M1015	_			Unknown	USA
Preferred Term	<u>Prod</u> ı	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>le Text</u>	<b>Duration</b>	<u>Mfr</u>	
Injection Site Injury; Wrong Technique In Product Usage Proces		n Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2015	11123154	EXPEDITED (15-DAY)		(	TC	US-MYLAN 2015M1015				Unknown	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2015	11130016	EXPEDITED (15-DAY)		(	DΤ	US-MYLAN 2015M1013	_			Unknown	USA



Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Device Failur Drug Ineffective; Inject Site Bruising; Injection Pain; Injection Site Swelling	e; Epipen	Auto-Injector Auto-Injector			S S	Intramuscular	0.3 Mg, 0.3 Mg,			Myl:	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-May-2015	11130029	EXPEDITED (15-DAY)			LT	SE-MYLANL 2015M10166				Unknown	SWE
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug neffective; Needle Iss Pain	Epipen ue;				S	Intramuscular	150 Mg	, Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2015	11137612	EXPEDITED (15-DAY)			ОТ	CA-MYLANI 2015M10167	-			Unknown	CAN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2015	11137625	EXPEDITED (15-DAY)			LT	US-MYLANI 2015M10162				Unknown	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Orug Ineffective	Epipen	Jr. Auto-Injector			S	Intramuscular	0.15 Mg	g, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-May-2015	11142819	EXPEDITED (15-DAY)			LT	CA-MYLANI 2015M10162	-			Unknown	CAN
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.



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Drug Ineffective	Epipen			S		Unk,	Once		Му	/lan	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	Age	<u>Sex</u>	Country
31-May-2015	11103005	EXPEDITED (15-DAY)			DE, OT	AU-MYLAN 2015M1015	-			Unknown	AUS
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Expir Product Administered	Injector	(Epinephrine) Auto 0.3 Mg			S		Unk, (	Once		Му	<i>r</i> lan
	Tramad	dol Hydrochloride			С		Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2015	11156928	EXPEDITED (15-DAY)			ОТ	GB-MYLAN 2015M1017				Unknown	SWE
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen				S		Unk			Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2015	10997498	EXPEDITED (15-DAY)			DE	CA-MYLAN 2015M1008	_			Unknown	CAN
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mfr	:
Expired Product Administered; Food Allergy	Epipen				S		Unk L	Jnk, Once		Му	/lan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2015	11160221	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2015M1017	-			Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Expired Product Administered; Injection Site Injury		Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	/lan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2015	10696066	EXPEDITED (15-DAY)		0	T	CA-MYLANL 2014M10161				Unknown	CAN
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Hypersensitivity; Inject Site Injury; Scar	Epipen ion Epinep				S S		Unk, O Unk, 2x			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jun-2015	11173302	EXPEDITED (15-DAY)		Н	IO, LT	US-MYLANL 2015M10175	_			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	, Prn		Myl	lan
FDA Received Date	Case #	Case Type	Health	Prof O	<u>Outcomes</u>	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2015	11175922	EXPEDITED (15-DAY)		0	T	US-MYLANL 2015M10177	_			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Injection Site Injury	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2015	11178908	EXPEDITED (15-DAY)		0	T	US-MYLANL 2015M10177				Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	, Once		Myl	lan
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Contro	<u></u> # lc	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2015	11178911	EXPEDITED (15-DAY)		0	OT US-MYLANLABS- 2015M1017970		_			Unknown	USA
Preferred Term	Produ	ct	Comp.	отс	Role	Route	Dosage	Toyt	Duration	Mfr	



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Accidental Exposure To		pipen Auto-Injector			S	Intramuscular	0.3 M	g, Once		Му	lan
Product; Crying; Injection Site Discolouration;	on Zo	oloft			С		Unk				
Injection Site		avix			С		Unk				
Hypoaesthesia; Skeleta Injury; Skin Exfoliation	al A	cebutolol			С		Unk				
injury, Skin Exicilation	М	etformin			С		Unk				
	Pı	rilosec /00661201/			С		Unk				
	Si	ngulair			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2015	11190060	EXPEDITED (15-DAY)			DE	CA-MYLANL 2015M10197				Unknown	CAN
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	E	pipen			S		Unk U	Jnk, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2015	11193391	EXPEDITED (15-DAY)			НО	ZA-MYLANL/ 2015M10186				Unknown	ZAF
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Device Failure	Eį	pipen Auto-Injector			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jun-2015	11199624	EXPEDITED (15-DAY)			ОТ	CA-PFIZER I K201000799	NC-			Male	CAN
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Injection Site Nerve Damage	o E	pipen Jr			S		0.15	Mg, Single		Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	I #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2015	11206332	EXPEDITED (15-DAY)			ОТ	US-MYLANL 2015M10191				Unknown	USA
Preferred Term	red Term Product		Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	



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Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, C	Once		Myla	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	<u>1#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2015	11206335	EXPEDITED (15-DAY)		H	Ю	US-MYLANL 2015M10193				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, C	Once		Myla	an
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	<u>1# 5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2015	11211897	EXPEDITED (15-DAY)		F	Ю	JP-MYLANLA 2015M10201	-			Unknown	JPN
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<b>Duration</b>	<u>Mfr</u>	
Stress Cardiomyopath	y Epipen				S	Intradermal	000 Epine	ered With 35ml Of	f	Myla	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contro	<u>1#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jun-2015	11218707	EXPEDITED (15-DAY)		C	T	US-MYLANL 2015M10199	-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Blood Pressu Decreased; Expired Product Administered; Injection Site Discolouration; Injectic Site Pallor; Loss Of Consciousness	ıre	Auto-Injector			S		Once			Myla	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contro	<u> 1#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
					_	US-MYLANL	A D.C.				USA
30-Jun-2015	11228836	EXPEDITED (15-DAY)		C	T	2015M10205				Unknown	USA



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Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2015	11229517	EXPEDITED (15-DAY)			LT	DE-MYLAN 2015M1006	-			Unknown	DEU
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; Needle Issue; Therapeutic Response Delayed	e Epipe	n Jr			S	Intramuscular	Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2015	11232245	DIRECT								Unknown	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Drug Dispensing Error	Epipe Epipe	n Jr. Auto-Injector n			S S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2015	10742537	EXPEDITED (15-DAY)			DE, OT	AU-MYLAN 2015M1000	-			Unknown	AUS
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Anaphylactic Reaction Drug Ineffective; Expir Product Administered		n (Epinephrine) Auto or 0.3 Mg			S	Intramuscular	Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2015	11243345	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2015M1021				Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Device Failur Injection Site Discolouration; Injection Site Injury; Injection Si	e; on	n Auto-Injector			S		0.3 M	g, Once		Myl	an



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Pallor	0#	0	1110-	Do-1 C		Mf- Otrail	# 500D F:	Die Ame	0	0
FDA Received Date		Case Type	Health		<u>Outcomes</u>	Mfr Control		<u>lity Age</u>	<u>Sex</u>	Country
08-Jul-2015	11247520	EXPEDITED (15-DAY)		C	DΤ	DK-MYLANLA 2015M102201	_		Unknown	DNK
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug Ineffective	Epipe	n 0,3 Mg/Dosis			S				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# <u>503B Faci</u>	<u>lity</u> <u>Age</u>	<u>Sex</u>	Country
13-Jul-2015	11267383	EXPEDITED (15-DAY)		C	T	US-MYLANLA 2015M102227			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure; Dyspno	oea Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	# <u>503B Faci</u>	<u>lity Age</u>	<u>Sex</u>	Country
14-Jul-2015	11270952	EXPEDITED (15-DAY)		C	T	US-MYLANLA 2015M102232			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Dyschromatopsia; Euphoric Mood; Facial Paralysis; Gait Deviatid Hyperacusis; Mydriasis Photophobia; Tremor	on;	n Auto-Injector			S		Unk, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# <u>503B Faci</u>	<u>lity</u> <u>Age</u>	<u>Sex</u>	Country
21-Jul-2015	11231911	EXPEDITED (15-DAY)		C	T	JP-MYLANLA 2015M102174	=		Unknown	JPN
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Laceration	Epipe	า			S	Intramuscular	0.15 Mg, Qd		My	lan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2015	11289903	EXPEDITED (15-DAY)		ОТ	-	US-MYLANL 2015M10231	-			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug	Epiper	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
Ineffective	Epiper	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof Ou	ıtcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2015	11291958	DIRECT	Υ	ОТ	-				71 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Administration En Injury Associated With Device		n Autoinjector 0.3 Mg			S					Lin	eage Therapeutics
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2015	11314899	EXPEDITED (15-DAY)		LT		US-MYLANL 2015M10244				Unknown	CAN
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Dyspno Heart Rate Irregular	oea; Epiper	1			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2015	11319570	EXPEDITED (15-DAY)		01	-	US-MYLANL 2015M10251	-			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T		Auto-Injector			S		0.3 Mg	յ, Unk		Му	rlan
Product; Device Failur Drug Ineffective; Inject Site Erythema		Auto-Injector			S	Intramuscular	-	g, Once		Му	lan



FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jul-2015	11323646	EXPEDITED (15-DAY)		C	T	JP-MYLANL 2015M10257	-			Unknown	JPN
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Expired Product Administered; Product Issue	Epiper Use	١			S	Intramuscular	0.3 Mg	, Daily		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2015	11323668	EXPEDITED (15-DAY)		C	CA, OT	AU-MYLANL 2015M10257	_			Unknown	AUS
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure Durir Pregnancy; Meningitis Neonatal		n (Epinephrine) Auto or 0.3 Mg			S	Transplacental	1 Df, To	otal		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2015	11057271	EXPEDITED (15-DAY)		C	T	US-MYLANL 2015M10126				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Device Failure	Epiper	n Jr. Auto-Injector			S	Intramuscular	0.15 M	g, Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Aug-2015	11347152	EXPEDITED (15-DAY)		C	T	JP-MYLANL 2015M10257	-			Unknown	JPN
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Accidental Exposure 1 Product; Injection Site Pallor; Poor Periphera Circulation		ı			S	Intramuscular				Му	rlan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Aug-2015	11368010	DIRECT		I	OS, HO, LT				52 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Mol Decreased; Necrotisinç Fasciitis					S	Intramedullar (bone marrow)	)				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Aug-2015	11365962	EXPEDITED (15-DAY)		(	TC	US-MYLANLA 2015M102386				Unknown	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Laceratio	n Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Aug-2015	11370981	EXPEDITED (15-DAY)		(	DΤ	CA-MYLANLA 2015M102664				Unknown	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Tremor	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Aug-2015	11362637	EXPEDITED (15-DAY)		(	TC	US-MYLANLA 2015M102587				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Injury	Epipen .	Jr. Auto-Injector			S	Intramuscular	0.15 N	/lg, Once		Myl	an
	Epipen .	Jr. Auto-Injector			S					Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Aug-2015	11389168	EXPEDITED (15-DAY)		(	DΤ	US-MYLANLA 2015M102684				Unknown	USA
Preferred Term	<u>Produc</u>	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	



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Device Failure	Epipen Jr. Auto-Injector				S	Intramuscular	0.15 Mg, Once		My	lan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Aug-2015	11389176	EXPEDITED (15-DAY)			ОТ	FI-MYLANLA 2015M10273			Unknown	FIN
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Jr			S				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Aug-2015	11409486	DIRECT							Unknown	
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Reaction To Excipient	Epi-Pe Auvi-C				S S					
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Aug-2015	11409732	EXPEDITED (15-DAY)			ОТ	US-MYLANL 2015M10282			Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Injection Site Bruising; Injection Site Laceration		n Jr. Auto-Injector			S	Intramuscular	0.15 Mg, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Aug-2015	11420106	DIRECT			ОТ			41 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Malfunction; Expired Product Administered; Heart R Increased; Heart Rate Increased; Injection Si Pain; Injury Associated With Device; Needle Is	te d	n Jr			S					



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2015	11422418	EXPEDITED (15-DAY)			НО	US-MYLANLA 2015M102839	-		11 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage <sup>-</sup>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Aug-2015	9359827	EXPEDITED (15-DAY)			ОТ	CA-ROCHE-1	205168		37 YR	Female	CAN
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphonia; Arthropathy; Diarrhoea; Dizziness;	Actemra	а			S	Intravenous (not otherwise specified	d)				
Fatigue; Food Allergy; Headache; Hypoaesthesia; Infecte	Actemra d	a			S	Intravenous (not otherwise specified	d)				
Skin Ulcer; Infusion Related Reaction;	Actemra	а			S	Intravenous (not otherwise specified	d)				
Laryngitis; Mouth Swell Nasopharyngitis; Oede Peripheral; Oropharyng	ma	a			S	Intravenous (not otherwise specified	d)				
Pain; Oxygen Saturation Decreased; Pruritus;	n Actemra	a			S	Intravenous (not otherwise specified	d)				
Rheumatoid Arthritis; Sialoadenitis; Tongue	Epipen				S	Unknown					
Discomfort; White Bloo Cell Count Increased	d Prednis Hydrox Palafer	ychloroquine			C C						
	Arava				С						
	Sulfasa Celebre				C C						
	Tylenol				č						
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Aug-2015	11434990	EXPEDITED (15-DAY)			ОТ	US-MYLANLA 2015M10282	-			Unknown	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	



Device Failure	Epipen	Epipen Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Sep-2015	11458663	EXPEDITED (15-DAY)		(	T	US-MYLANI 2015M1028	-			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 M	g, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Sep-2015	11419073	EXPEDITED (15-DAY)		H	Ю	US-MYLANI 2015M1027				Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Sep-2015	11469842	EXPEDITED (15-DAY)		(	T	CA-MYLANI 2015M1029				Unknown	CAN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Sep-2015	11469860	EXPEDITED (15-DAY)		(	TC	SE-MYLANI 2015M1023				Unknown	SWE
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Produc Quality Issue	ct Epipen				S					Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Sep-2015	11469869	EXPEDITED (15-DAY)		(	TC	SE-MYLANI 2015M1029				Unknown	SWE
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mfr	

Date - Time: 15-May-2018 01:32:07 PM EST

Note: If the field is blank, there is no data.

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Orug Ineffective; Expired Epipen Product Administered			S						Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Sep-2015	11482577	DIRECT			HO, LT			51 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Arrhythmia; Migraine; Myocardial Necrosis Marker Increased; Nuc Magnetic Resonance Imaging Abnormal	Ziac	ril an C D3			s ccccccc	Intramuscular	Hospital Unk At Hospital			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Sep-2015	11498051	EXPEDITED (15-DAY)			ОТ	US-MYLANLA 2015M102959	=		Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Sep-2015	11496209	EXPEDITED (15-DAY)			DE, HO	AU-MYLANLA 2015M103085			Unknown	AUS
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Expired Product Administered	; Epipen Injector	(Epinephrine) Auto 0.3 Mg			S		Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Sep-2015	11503552	EXPEDITED (15-DAY)			ОТ	US-MYLANLA 2015M102979			Unknown	USA



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Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Injury Associated With Device	Epipen	Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Sep-2015	11503556	EXPEDITED (15-DAY)		C	T	US-MYLAN 2015M1029				Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Orug Ineffective; Injecti Site Bruising	ion Epipen	Auto-Injector			S	Intramuscular	0.3 N	lg, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Sep-2015	11517500	EXPEDITED (15-DAY)		H	IO, OT	CA-MYLAN 2015M1028				Unknown	CAN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Device Failure; Expired Product Administered	d Epipen Epipen				s s	Intramuscular		lg, Unk lg, Unk		Myl Myl	
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Sep-2015	11520443	DIRECT							5 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Expired Product Administered; Inability Afford Medication; Proc Quality Issue; Stress		n Jr			S		Into T	he Outer Thigh			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Sep-2015	11467958	EXPEDITED (15-DAY)		C	T	SE-MYLAN 2015M1029				Unknown	SWE
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen				S			lg, Unk		Myl	<b>.</b>



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Sep-2015	11522271	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2015M103				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipen /	Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Sep-2015	11529421	EXPEDITED (15-DAY)			DE	JP-MYLAN 2015M103	_			Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Death	Epipen				S	Intramuscular				Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Sep-2015	11537761	EXPEDITED (15-DAY)			ОТ	DK-MYLAN 2015M103				Unknown	DNK
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen				S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Sep-2015	11540006	EXPEDITED (15-DAY)			НО	AU-MYLAN 2015M103				Unknown	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction		(Epinephrine) Auto			S		300 N	lg, Unk		Myl	an
Device Failure; Expired Device Used		(Epinephrine) Auto			S		300 M	lg, Unk		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Sep-2015	11547308	EXPEDITED (15-DAY)			HO, OT	US-MYLAN 2015M103				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	



Drug Ineffective	Epipen /	Epipen Auto-Injector			S	Intramuscular	0.3 l	Mg, Once		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Sep-2015	11547399	EXPEDITED (15-DAY)		F	Ю	FI-MYLA 2015M10				Unknown	FIN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	g <u>e Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen .	Jr			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
28-Sep-2015	11539562	EXPEDITED (15-DAY)		D	ÞΕ	JP-MYLA 2015M10				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mfr	
Death	Epipen				S					Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Sep-2015	11564067	EXPEDITED (15-DAY)		C	T	US-MYLA 2015M10				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Device Failure; Drug Ineffective	Epipen /	Auto-Injector			S		Unk	, Prn		My	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Sep-2015	11573029	EXPEDITED (15-DAY)		C	T	BE-MYLA 2015M10				Unknown	BEL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	g <u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure; Needle	Epipen				S		0.3	Mg, Unk		Му	/lan
Issue	Epipen				S		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Oct-2015	10593127	EXPEDITED (15-DAY)		F	IO, OT	US-MYLA 2014M10				Unknown	USA
Preferred Term	Produc	t	Comp.	OTC	Role	Route	Dosa	ge Text	<b>Duration</b>	Mfr	

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Injury Associated With Epipen Auto-Injector Device Epipen Auto-Injector					S		Unk			Myl	
Device	Epipen	Auto-Injector			S		0.3 M	g, Prn		Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Oct-2015	11590265	EXPEDITED (15-DAY)		l	.T	DK-MYL 2015M10				Unknown	DNK
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen				S	Intramuscular				Myl	lan
	Alk Eng Bricany Aerius Prednis Solu-M Tavegy	solon edrol			C C C C C						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Oct-2015	11590270	EXPEDITED (15-DAY)		ŀ	Ю	JP-MYLA 2015M1(				Unknown	JPN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure To Product By Child; Expir Product Administered; Injection Site Pallor					S		Unk			Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Cor	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Oct-2015	11599172	EXPEDITED (15-DAY)		(	DΤ	AT-MYL/ 2015M10				Unknown	AUT
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Device Failure; Device Malfunction	Epipen				S					Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Cor	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Oct-2015	11608428	EXPEDITED (15-DAY)		(	DΤ	US-MYL 2015M10				Unknown	USA



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 M	g, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Oct-2015	11623456	DIRECT								Unknown	USA
<u>Preferred Term</u>	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Product Label Confusi	on Epipen				S	Intramuscular				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2015	11618870	EXPEDITED (15-DAY)		C	T	US-MYLAN 2015M103				Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T		Auto-Injector			S		0.3 M	g, Once		Му	lan
Product; Apathy; Atten Deficit/Hyperactivity Disorder; Condition Aggravated; Heart Rat Increased; Injection Si Pallor; Mood Altered; Panic Attack	e e				С		0.5 M	g, Qd			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Oct-2015	11629410	DIRECT		R	ll.				7 YR	Male	USA
Preferred Term	Produc	<u>2t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Extra Dose Administer Needle Issue; Syringe Issue; Syringe Issue		1			800000						



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

A-Oct-2015								- 1				
Product   Comp.   OTC   Role   Route   Dosage Text   Duration   Mfr	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Solution	14-Oct-2015	11629769	EXPEDITED (15-DAY)		0	Г					Unknown	JPN
recreased: Headache; lyposesthesia; arraesthesia; arraesth	Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Teferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  DATE Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DOTAL Role Route Dosage Text Duration Mfr  DATE OF A Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DOTAL Role Route Dosage Text Duration Mfr  DATE OF A Role Route Dosage Text Duration Mfr  DOTAL Role Route Dosage Text Duration Mfr  D	Blood Pressure Decreased; Headache Hypoaesthesia; Paraesthesia		1			S	Intramuscular	0.3 Mg	g, Single		Myl	an
referred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  evice Failure Epipen Auto-Injector S Intramuscular 0.3 Mg, Once Mylan  EDA Received Date Case # Case Type Health Prof Outcomes OTC Role Route Dosage Text Unknown USA  Product Comp. OTC Role Route Dosage Text Duration Mfr  evice Failure; Drug Epipen Auto-Injector S Unk Unk, Once Mylan  erice Failure; Drug Epipen Auto-Injector S Unk Unk, Once Mylan  erice Failure; Drug Epipen Auto-Injector S Unk Unk, Once Mylan  erice Failure; Drug Epipen Auto-Injector S Unk Unk, Once Mylan  erice Failure; Drug Epipen Epipen Auto-Injector S Unk Unk, Once Mylan  erice Failure; Drug Epipen E	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Levice Failure Epipen Auto-Injector S Intramuscular 0.3 Mg, Once Mylan  EDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  19-Oct-2015 11603941 EXPEDITED (15-DAY) OT US-MYLANILABS- 2015M1033554 Unk Unk, Once Mylan  Expression Auto-Injector S Unk Unk, Once Mylan  Epipen Auto-Injector S Unk Unk, Once Mylan  EDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  19-Oct-2015 11640261 EXPEDITED (15-DAY) OT AU-MYLANILABS- 2015M1035805  Epipen (Epinephrine) Auto Injector O.3 Mg Hydrocortisone C  EDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  10-Oct-2015 11640261 EXPEDITED (15-DAY) OT AU-MYLANILABS- 2015M1035805  Epipen (Epinephrine) Auto Injector 0.3 Mg Hydrocortisone C  EDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  19-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANILABS-  19-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANILABS-  19-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANILABS-  10-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANILABS-  1	15-Oct-2015	11634534	EXPEDITED (15-DAY)		0	Γ					Unknown	USA
FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Country   9-Oct-2015   11603941   EXPEDITED (15-DAY)   OT   US-MYLANLABS-2015M1033554   Unknown   USA   10-Oct-2015   11603941   EXPEDITED (15-DAY)   OT   Role   Route   Dosage Text   Duration   Mfr   10-Oct-2015   Duration   Mfr	Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
9-Oct-2015 11603941 EXPEDITED (15-DAY) OT US-MYLANLABS- 2015M1033554  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Device Failure; Drug Epipen Auto-Injector S Unk Unk, Once Mylan  DAR Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  P-Oct-2015 11640261 EXPEDITED (15-DAY) OT AU-MYLANLABS- 2015M1035805 Unk Unk, Once Mylan  AUS  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Italaise; Paraesthesia Epipen (Epinephrine) Auto Injector 0.3 Mg Hydrocortisone C  DAR Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Mylan  Mylan  Mylan  Mylan  Mylan  Mylan  Talaise; Paraesthesia Epipen (Epinephrine) Auto Injector 0.3 Mg Hydrocortisone C  DAR Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  DAR Product Case # Case Type Ad	Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Myl	an
referred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  effective S Unk Unk, Once Mylan  effective S S S S S S S S S S S S S S S S S S S	FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contr	ol#	503B Facility	Age	Sex	Country
Periodic Failure; Drug Epipen Auto-Injector S Unk Unk, Once Mylan  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  19-Oct-2015 11640261 EXPEDITED (15-DAY) OT AU-MYLANLABS- 2015M1035805 Unknown AUS  10-Oct-2015 Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  10-Oct-2015 S 1 Df, Unk Mylan  10-Oct-2015 Injector 0.3 Mg	19-Oct-2015	11603941	EXPEDITED (15-DAY)		0	Γ					Unknown	USA
reffective  TDA Received Date	Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
9-Oct-2015 11640261 EXPEDITED (15-DAY) OT AU-MYLANLABS-2015M1035805 Unknown AUS  Treferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Malaise; Paraesthesia Duration Mylan Injector 0.3 Mg Hydrocortisone C  TOA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  19-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANLABS- Unknown ZAF	Device Failure; Drug Ineffective	Epiper	Auto-Injector			S		Unk U	nk, Once		Myl	an
referred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Malaise; Paraesthesia Epipen (Epinephrine) Auto Injector 0.3 Mg Hydrocortisone C  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  19-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANLABS- Unknown ZAF	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Malaise; Paraesthesia Epipen (Epinephrine) Auto S 1 Df, Unk Mylan Injector 0.3 Mg Hydrocortisone C  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  19-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANLABS- Unknown ZAF	19-Oct-2015	11640261	EXPEDITED (15-DAY)		0	Γ					Unknown	AUS
Pral Injector 0.3 Mg Hydrocortisone C  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  19-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANLABS- Unknown ZAF	Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
19-Oct-2015 11641792 EXPEDITED (15-DAY) HO ZA-MYLANLABS- Unknown ZAF	Malaise; Paraesthesia Oral	Injecto	r 0.3 Mg					1 Df, U	Jnk		Myl	an
10 000 2010 11011102 270 2711 110	FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	Sex	Country
	19-Oct-2015	11641792	EXPEDITED (15-DAY)		Н	0		_			Unknown	ZAF



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	_					_	-	_			
Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epip	en Auto-Injector			S					Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Oct-2015	11579688	EXPEDITED (15-DAY)			НО	JP-MYLAN 2015M103				Unknown	JPN
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Blood Pressure Increas	sed; Epip	en			S	Intramuscular	1 Df, S	Single		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
20-Oct-2015	11648197	DIRECT			ОТ				69 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Malfunction; Device Use Error; Nee Issue	Epip edle	en			S						
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Oct-2015	10368760	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014S1015				Unknown	USA
Preferred Term	Pro	duct	Comp.	OTC	<u>Role</u>	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Injection Site Laceration		en Jr. Auto-Injector			S	Intramuscular	.15 Mg	g,Once		Myl	an
Scar; Wrong Technique Product Usage Proces	.ς ⊏bih	en Jr. Auto-Injector ivitamin			S C		Unk			Myl	an
	Fish	Oil			С		Unk				
	Mela	atonin			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Oct-2015	10419847	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014S1016				Unknown	USA



In Product Usage Process

#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

S Injection Site Laceration; Epipen Jr. Auto-Injector Mylan Unk Wrong Technique In **Product Usage Process** FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # 503B Facility Age **Sex** Country US-MYLANLABS-21-Oct-2015 11644780 **EXPEDITED (15-DAY)** OT Unknown USA 2014M1003347 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text Duration** Mfr S Injection Site Laceration; Epipen Jr. Auto-Injector Mylan Unk Wrong Technique In Product Usage Process FDA Received Date Case # **Health Prof Outcomes** Case Type Mfr Control # 503B Facility Age Sex Country 21-Oct-2015 11650703 **EXPEDITED (15-DAY)** OT **US-MYLANLABS-**Unknown USA 2014M1003351 **Preferred Term Product** Comp. OTC Role Route **Dosage Text** Duration Mfr S Injury Associated With Epipen Jr. Auto-Injector Mylan Unk Device FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # **503B Facility** <u>Age</u> Sex Country US-MYLANLABS-11650738 **EXPEDITED (15-DAY)** OT 5 YR USA 21-Oct-2015 Male 2014S1016280 **Preferred Term Product** Comp. **OTC** Role **Route Dosage Text Duration** Mfr S Epipen Jr. Auto-Injector Accidental Exposure To Mylan Unk Product; Injury Associated With Device FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Sex Country Age 21-Oct-2015 11650739 **EXPEDITED (15-DAY)** OT US-MYLANLABS-Unknown USA 2014M1003352 **Preferred Term Product** Comp. **OTC** Role Mfr Route **Dosage Text** Duration Injury Associated With Epipen Auto-Injector S Mylan Intramuscular Unk Device: Wrong Technique



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
21-Oct-2015	11650741	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014M1003	_			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Injury Associated With Device	Epiper	n Jr. Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Oct-2015	11650742	EXPEDITED (15-DAY)		1	ОТ	US-MYLAN 2014S1016	_			Unknown	USA
Preferred Term	<u>Produ</u>	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Eating Disorder; Injection Site Laceration; Injection S Scar; Post-Traumatic Stress Disorder	)	n Jr. Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Oct-2015	11650744	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2014S1016	_			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Laceration	on Epiper	n Jr. Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Oct-2015	11451893	EXPEDITED (15-DAY)			HO, OT	US-MYLAN 2015M1029				Unknown	CAN
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Injur Associated With Devic	у	n Jr			S	Intramuscular	Unk U	Ink, Prn		Myl	an



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	I# 503B Facil	ity Age	<u>Sex</u>	Country
26-Oct-2015	11469867	EXPEDITED (15-DAY)		(	ОТ	FR-MYLANL 2015M10302			Unknown	FRA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen				S		0.15 Mg / 0.3 MI		Myla	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	I# 503B Facil	ity Age	<u>Sex</u>	Country
26-Oct-2015	11663366	DIRECT						2 YR	Male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Medical Device Site Laceration; Scar	Epipen	Jr 0.15			S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	I# 503B Facil	ity <u>Age</u>	<u>Sex</u>	Country
26-Oct-2015	11663379	DIRECT	Υ					3 YR	Male	
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Keloid Scar; Medical Device Site Laceration		Jr 0.15 Mg			S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	I# 503B Facil	ity Age	<u>Sex</u>	Country
26-Oct-2015	11664093	DIRECT	Υ					3 YR	Unknown	
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Medical Device Site Laceration; Needle Iss Scar	Epipen sue;				S					
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	I# 503B Facil	ity Age	<u>Sex</u>	Country
26-Oct-2015	11664102	DIRECT	Υ					11 YR	Male	
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	

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S Device Malfunction: Epipen Medical Device Site Laceration: Needle Issue FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Age **Sex Country** Υ 26-Oct-2015 11664114 DIRECT 3 YR Male **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text** Duration Mfr S Medical Device Site **Epipen** Laceration; Needle Issue; Scar FDA Received Date Case # **Health Prof Outcomes** Case Type Mfr Control # 503B Facility <u>Age</u> Sex Country 26-Oct-2015 11664135 DIRECT 3 YR Male **Preferred Term** Role **Product** Comp. OTC Route **Dosage Text** Duration Mfr S Medical Device Site **Epipen** Laceration; Scar; Wrong Technique In Product **Usage Process** FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Age Sex Country 26-Oct-2015 11664292 DIRECT Υ 2 YR Male **Preferred Term Dosage Text Product** Comp. OTC Role Route Duration Mfr S Medical Device Site Epipen Laceration; Scar FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Sex **Country** <u>Age</u> Υ 26-Oct-2015 11664303 DIRECT 5 YR Male **Preferred Term Product OTC** Role **Dosage Text Duration** Mfr Comp. Route S Medical Device Site **Epipen** Laceration; Wrong Technique In Product

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Usage Process	C#	Casa Tura	Health	Drof O		Min Control d	FOOD Facility	A	Cov	Country
FDA Received Date		Case Type		Prot U	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Oct-2015	11664831	DIRECT	Y					4 YR	Male	
Preferred Term	Prod	<u>uct</u>	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Medical Device Site Laceration; Scar	Epipe	en			S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
26-Oct-2015	11672157	DIRECT	Υ					2 YR	Male	
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Injection Site Injury; Laceration; Wrong Technique In Product Usage Process	Epipe	n Jr			S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
26-Oct-2015	11672287	DIRECT	Υ					1 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dyskinesia; Injection S Injury; Laceration; Nee Issue; Scar		en Jr			S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
26-Oct-2015	11672342	DIRECT	Υ					1 YR	Male	
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Injection Site Injury; Laceration; Needle Iss	Epipe sue	en			S					Mylan

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Oct-2015	11682266	EXPEDITED (15-DAY)		0	ÞΕ	AU-MYLANLA 2015M103767				Unknown	AUS
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Anaphylactic Reaction		en (Epinephrine) Auto or 0.3 Mg			S	Intramuscular	Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Oct-2015	11404136	EXPEDITED (15-DAY)		C	T	FR-MYLANLA 2015M102256				Unknown	FRA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Arthralgia; Inflammatio	n; Epipe	en Jr			S		1 Df,	Unk		Му	lan
Intentional Product Misuse; Myalgia	Cortis Lanso	sone oprazole			C C		60 Mg	g, Qd			
	Mizol	len			С		20 Mg	g, Qd			
	Panto	pprazole			С		80 Mg	g, Qd			
	Monte	elukast			С		10 Mg	g, Qd			
	Prima	alan			С		10 Mg	g, Qd			
	Terbu	utalin /00199201/			С		Unk,	Tid			
	Valad	ciclovir			С		1000	Mg, Qd			
	Vento	olin /00139501/			С		Unk,	Prn			
	Bude	sonide			С		Unk,	Tid			
	Predr	nisone			С		7 Mg,	Qd			
	Tram	adol			С		300 N	lg, Qd			
	Innov	air			С		2 Unk	x, Bid			
	Kaled	orid			С		600 N	lg, Qd			
	Fexo	fenadine			С		360 N	lg, Qd			
FDA Received Date	Case #	Case Type	Health	Prof C	<u>utcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Nov-2015	11690279	EXPEDITED (15-DAY)		C	T	IE-MYLANLAI 2015M103652				Unknown	IRL

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Preferred Term	Produc	<u></u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen				S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Nov-2015	11692365	DIRECT		Ι	OS, HO, LT,	RI			16 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Reaction; Necrotising Myositis; Septic Shock	; Epi Pen	Mylan			S	Intramuscular	One T	ime Use		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Nov-2015	11694758	EXPEDITED (15-DAY)		(	DΤ	JP-MYLAN 2015M1038				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Asthma; Chest Pain	Epipen				S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Nov-2015	11696338	EXPEDITED (15-DAY)		[	DE	JP-MYLAN 2015M1037	-			Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Death	Epipen				S	Intramuscular	Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Nov-2015	11705939	EXPEDITED (15-DAY)		L	.T	AU-MYLAN 2015M1039				Unknown	AUS
<u>Preferred Term</u>	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Device Failure	Epipen . Injector	Jr Adrenaline Auto-			S	Intramuscular	150 M	lg, Unk		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Nov-2015	11716512	EXPEDITED (15-DAY)		(	DΤ	US-MYLAN 2015M1038				Unknown	USA

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Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Wron	g Epipen	Auto-Injector			S	Subcutaneous	0.3 Mg	ı, Once		Myl	an
Technique In Product Usage Process	Depako	ote			С	Oral	Unk				
ouge i ioooo	Zoloft				С	Oral	Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Nov-2015	11512409	EXPEDITED (15-DAY)		C	T	JP-MYLANL 2015M1031				Unknown	JPN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Contusion; Off Label U Product Quality Issue	lse; Epipen				S	Intramuscular	0.15 M	lg, As Needed		Myl	an
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof O	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Nov-2015	11719354	EXPEDITED (15-DAY)		С	T	US-MYLAN 2015M1033	-			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S		Unk Uı	nk, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes (	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Nov-2015	11719378	EXPEDITED (15-DAY)		С	T	US-MYLAN 2015M1037				Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Produ Administered; Injection Site Pain; Injury Associated With Devic	uct	Auto-Injector			S	Intramuscular	0.3 Mg	ı, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Nov-2015	11742283	EXPEDITED (15-DAY)		С	T	US-MYLAN 2015M1038				Unknown	USA



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Device Failure	Epipen	Jr. Auto-Injector			S	Intramuscular	0.15 N	lg, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Nov-2015	11743616	EXPEDITED (15-DAY)		(	ЭТ	US-MYLANLA 2015M10394	-			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug Ineffective	Epipen	Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Nov-2015	11743932	EXPEDITED (15-DAY)		I	DE, LT, OT	AU-PFIZER II K201000918	NC-		49 YR	Female	AUS
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	Mfr	
Clostridial Infection; Crepitations; Gas Gangrene; Injection Site Infection; Injection Site Pain; Purulence; Seps Skin Discolouration	e Prednis	hazine			S S C	Intramuscular	-	g, Single , Single , Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Nov-2015	11347153	EXPEDITED (15-DAY)		(	TC	FR-MYLANLA 2015M10259 <sup>2</sup>				Unknown	FRA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Device Failure; Needle Issue	e Epipen				S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Nov-2015	11751927	EXPEDITED (15-DAY)		(	TC	US-MYLANLA 2015M103892	-			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	յ, Prn		Myl	an



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Nov-2015	11755502	EXPEDITED (15-DAY)		0	Т	US-MYLAN 2015M1031	_			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Blood Pressul ncreased; Expired Product Administered; Heart Rate Increased; njection Site Pain; Inju Associated With Device	re	n Jr. Auto-Injector			S		Unk	Unk, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
20-Nov-2015	11753840	EXPEDITED (15-DAY)		Н	O, LT	AU-MYLAN 2015M1041				Unknown	AUS
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure		n (Epinephrine) Auto or 0.3 Mg			S	Intramuscular	300	Mg, Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Nov-2015	11701720	EXPEDITED (15-DAY)		0	Т	JP-MYLANI 2015M1038				Unknown	JPN
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<b>Duration</b>	<u>Mfr</u>	
njection Site Laceratio	n; Epipe	n			S	Intramuscular	0.15	Mg, Single		Му	lan
Product Quality Issue; Vrong Technique In	Alesio	on			С	Oral		lg, Total			
Product Usage Proces	s Sultar	nol			С		Unk				
	Predo	onine /00016201/			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Nov-2015	11457256	NON-EXPEDITED				PHEH2014	US012092			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Allergy To Arthropod		on Patch			S	Transdermal	1 Df (4.6 Mg), Per Day		Nov	vartis
Sting; Balance Disorde Dizziness; Gait	er; Exelo	on Patch			S	Transdermal	9.5 Mg, Unk		Nov	vartis
Disturbance; Influenza	Epipe	en			S	Unknown	-			
Like Illness; Malaise; Memory Impairment; C	Ceta	phil			С	Unknown	Unk Ukn, Unk			
Label Use; Product	Carb	idopa Levodopa			С	Unknown				
Adhesion Issue;	Flutio	casone			С	Unknown				
Seborrhoea	Spiro	onolactone			С	Unknown				
	Pant	oprazole			С	Unknown				
	Ropi	nirole			С	Unknown				
	Sertr	aline			С	Unknown				
	Valiu	ım			С	Unknown				
	Citra	cal			С	Unknown				
	Vitan	nin A			С	Unknown				
	Vitan	min D3			С	Unknown				
	Coq1	10			С	Unknown				
	Multi	Vitamin			С	Unknown				
	Aspii	rin			С	Unknown				
	Stoo	l Softener			С	Unknown				
	Miral	lax			С	Unknown				
	Gink	go Biloba			С	Unknown				
	Niaci	in			С	Unknown				
	Vitan	nin D Nos			С	Unknown				
	Equa	ate Pain Reliever			С	Unknown				
		ate Pain Reliever			С					
	Fish	OII			С	Unknown				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
29-Nov-2015	11587648	EXPEDITED (15-DAY)			ОТ	JP-MYLANLA 2015M103270			Unknown	JPN
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	



Drug Effect Incomplete	e Epipen				S	Intramuscular	Unk		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	# 503B Facility	<u>y Age</u>	<u>Sex</u>	Country
30-Nov-2015	11789781	DIRECT	Υ	0	T			60 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Discolouration; Injection Site Pain; Injury Associated With Device	on .	n			S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Dec-2015	11795081	EXPEDITED (15-DAY)		0	T	US-MYLANL 2014M10033			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Laceration	on; Epipen	Jr. Auto-Injector			S		Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Dec-2015	11805247	EXPEDITED (15-DAY)		0	T	AU-MYLANL 2015M10418	=		Unknown	AUS
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mfr	
Device Failure		(Epinephrine) Auto 0.3 Mg			S	Intramuscular	Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Dec-2015	11824480	EXPEDITED (15-DAY)		Ľ	Т	US-MYLANL/ 2015M10431	_		Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Effect Incomplete	e Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Unk		Myl	an

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Dec-2015	11824491	EXPEDITED (15-DAY)		(	DΤ	US-MYLANI 2015M1043	_			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Blood Pressu Increased; Heart Rate Increased; Injection Si Bruising; Injection Site Ischaemia; Injection S Pain; Injury Associated With Device; Wrong Technique In Product Usage Process	ire te ite	n Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Dec-2015	11389177	EXPEDITED (15-DAY)		(	DT	US-MYLANI 2015M1026	_			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Dec-2015	11849423	EXPEDITED (15-DAY)		(	TC	US-MYLANI 2015M1043				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Device Failur		n Auto-Injector			S		Prn			Myl	an
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Dec-2015	11849429	EXPEDITED (15-DAY)		(	DΤ	US-MYLANI 2015M1044:	_			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<b>Duration</b>	Mfr	
Injection Site Laceration Scratch	on; Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15	Mg, 2x		Myl	an

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	Benadry			С		Unk, Once		Myl	an	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Dec-2015	11855289	EXPEDITED (15-DAY)			DE	JP-MYLANLA 2015M10461	_		Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Neoplasm Malignant	Epipen				S	Intramuscular	0.3 Mg, Single		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Dec-2015	11844522	EXPEDITED (15-DAY)			ОТ	SE-MYLANL/ 2015M10452			Unknown	SWE
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure	Epipen				S		Daily Dose: 1 Df Dosage Form Every Total		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Dec-2015	11880079	EXPEDITED (15-DAY)			ОТ	IE-MYLANLA 2015M10472	=		Unknown	IRL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen				S				Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jan-2016	11893273	EXPEDITED (15-DAY)			НО	AU-MYLANL/ 2015M10470			Unknown	AUS
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen Injector	(Epinephrine) Auto 0.3 Mg			S		Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jan-2016	11913910	EXPEDITED (15-DAY)			ОТ	IE-MYLANLA 2016M10019			Unknown	IRL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	

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							- 1				
Device Failure; Device Malfunction	e Epipen				S		0.3 Mg	, Unk		N	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jan-2016	11913911	EXPEDITED (15-DAY)		(	DΤ	IE-MYLANL 2016M1001				Unknown	IRL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Device Failure	Epipen				S		0.3 Mg	, Unk		N	lylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jan-2016	11916130	EXPEDITED (15-DAY)		(	DΤ	IE-MYLANL 2016M1002				Unknown	IRL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Device Failure	Epipen				S					N	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jan-2016	11925218	EXPEDITED (15-DAY)		(	DΤ	JP-MYLANL 2016M1002				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product; Blood Pressu Increased; Expired Product Administered; Injection Site Pain; Injection Site Pallor; Palpitations	re				S		Unk			M	lylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jan-2016	11888531	EXPEDITED (15-DAY)		H	HO, LT	GB-MYLAN 2016M1000			48 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Device Failure	Epipen				S	Intramuscular	0.3 Mg	, Unk		M	lylan
	Mebeve				С						lylan



FDA Received Date	10 B 6 B 6						
	ealth Prof Out	comes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jan-2016 11972278 EXPEDITED (15-DAY)	ОТ		US-MYLANLAB 2016M1002844			Unknown	USA
<u>Preferred Term</u> <u>Product</u> <u>Comp</u>	mp. OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Loss Of Epipen Auto-Injector Consciousness		S		Unk, 2x		Myl	an
FDA Received Date	ealth Prof Out	comes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jan-2016 10755133 EXPEDITED (15-DAY)	HO,	, LT	SE-MYLANLAB 2015M1002547			Unknown	SWE
Preferred Term Product Comp	mp. OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug Epipen (Epinephrine) Auto Ineffective; Needle Issue; Injector 0.3 Mg Wrong Technique In		S	Intramuscular	0.3 Mg, Separate Dosages/ Interval: 4 In 1 Days		Myl	an
Product Usage Process Betapred		С		Unk		Myl	an
Pulmicort		C C				Myl	
Bricanyl Aerius /01009701/		С		Unk		Myl. Myl.	
Aerius /01009701/		C		Sep Doses/Interval 4 In 1 Days		iviyi	all
FDA Received Date	ealth Prof Out	comes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Feb-2016 11987229 DIRECT						Unknown	USA
Preferred Term Product Comp	mp. OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Drug Dispensing Error; Epipen Epinephrine Drug Dispensing Error;		S		Injectable, Injection, Trainer Units			
Drug Ineffective; Expired Epipen (Epinephrine) Product Administered		S		Injectable, Injection			
FDA Received Date	ealth Prof Out	comes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Feb-2016 12067293 DIRECT					4 YR	Female	USA
Preferred Term Product Com	np. OTC	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	Mfr	

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Injection Site Bruising; Injection Site Pain; Ne Issue; Needle Issue; Needle Issue; Pain In Extremity	edle Qvar Albute Fluori Probio	erol de Tablets			8 C C C C C					M	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2016	12077245	EXPEDITED (15-DAY)		C	T	US-MYLAN 2016M1005				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mf	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	յ, Prn		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	9912011	NON-EXPEDITED				US-MYLAN 2013275228				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mf</u>	[
Drug Hypersensitivity	Epipe	n Auto-Injector			S		Unk			My	/lan
	Zoloft				S		Unk			M	/lan
	Tetrad	cycline			S		Unk			M	/lan
	Morph	nine Sulfate			S		Unk			My	/lan
	Paxil				S		Unk			M	/lan
	Zofrar	n /00955301/			S		Unk			My	/lan
	Vitam	in B			S		Unk			My	/lan
	Tetan	us Vaccine			S		Unk			M	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	10822614	NON-EXPEDITED				US-MYLAN 2014M1013	-		67 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mf	
Device Failure	evice Failure Epipen Auto-Injector				S	Intramuscular	0.3mg	, Prn		My	ylan



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u> Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	11458662	EXPEDITED (15-DAY)		ŀ	НО	US-MYLAN 2015M1028			19 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Dyspnoea	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		ľ	Mylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083204	NON-EXPEDITED				US-MYLAN 2015M1010			48 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure; Eye Swelling	Epiper	n Auto-Injector			S	Intramuscular	0.3 M	g, Once		١	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
17-Feb-2016	12083207	NON-EXPEDITED				US-MYLAN 2015M1011				Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product By Child	o Epiper	n Jr. Auto-Injector			S		Unk			١	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083217	NON-EXPEDITED				US-MYLAN 2015M1014			37 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		<u> </u>	Mylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083221	NON-EXPEDITED				US-MYLAN 2015M1013	_			Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Accidental Exposure T	o Epiper	n Jr. Auto-Injector			S		Unk, (	D		N	Mylan

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Product; Expired Product Administered; Injection

Site Pain

FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083225	NON-EXPEDITED				US-MYLAN 2015M101				Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		1	Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083226	NON-EXPEDITED				US-MYLAN 2015M101				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		1	Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083227	NON-EXPEDITED				US-MYLAN 2015M1012				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Accidental Exposure 1 Product	Го Еріре	n Auto-Injector			S		Unk, C	Once		1	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083238	NON-EXPEDITED				US-MYLAN 2015M1000				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		1	Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083240	NON-EXPEDITED				US-MYLAN 2014M1015			18 YR	Male	USA



Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	M	<u>lfr</u>
Device Failure		en Auto-Injector erol /00139501/			S C	Intramuscular Respiratory (inhalation)		Mylan Mylan		
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083243	NON-EXPEDITED				US-MYLAN 2015M1000		37 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Device Failure; Expire Product Administered	d Epipe Mariji	en Auto-Injector uana			S C	Intramuscular	0.3 Mg, Prn Unk			Лylan Лylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083246	NON-EXPEDITED				US-MYLAN 2014M1016		3 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Accidental Exposure T Product By Child	o Epipe	en Jr. Auto-Injector			S	Subcutaneous	0.15 Mg, Unk		N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
17-Feb-2016	12083257	NON-EXPEDITED				US-MYLAN 2015M1001			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Accidental Exposure T Product	o Epipe	en Auto-Injector			S		Unk Unk, Once		N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083260	NON-EXPEDITED				US-MYLAN 2015M1002			Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Accidental Exposure T Product	o Epipe	en Auto-Injector			S	Intramuscular	Unk		N	Mylan

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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083266	NON-EXPEDITED				US-MYLANI 2015M1002	_			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
No Adverse Event; Off	f Epipe	n Jr. Auto-Injector			S		Unk			Му	rlan
Label Use	Epipe	n Jr. Auto-Injector			S					Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083272	NON-EXPEDITED				US-MYLANI 2015M1002			7 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	Mfr	
Injection Site Laceration	on Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083274	NON-EXPEDITED				US-MYLANI 2015M1000			2 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T		n Auto-Injector			S		Unk I	Mg, Unk		Му	rlan
Product By Child; Injection Site Bruising; Injection Injury		ins /00067501/			С		Unk			Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083276	NON-EXPEDITED				US-MYLANI 2015M1002				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	Unk			Му	rlan e
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083277	NON-EXPEDITED				US-MYLANI 2015M1001				Unknown	USA



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Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Contusion	Epipe	n Trainer			S		Unk			M	lylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>utcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083278	NON-EXPEDITED				US-MYLAN 2015M100	-			Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product; Injection Site Pain; Injection Site Pa Unevaluable Event		n Auto-Injector			S		Unk			M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083279	NON-EXPEDITED				US-MYLAN 2015M100			3 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product; Injection Site Pain		n Jr. Auto-Injector			S		Unk U	Ink		M	lylan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083281	NON-EXPEDITED				US-MYLAN 2015M100	-		38 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Abdominal Pain Upper Accidental Exposure T Product; Diarrhoea; Nausea; Nervousness Pyrexia	Го	n Jr. Auto-Injector			S	Intramuscular	0.15 N	/lg, Once		M	lylan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083293	NON-EXPEDITED				US-MYLAN 2015M100	_			Female	USA
Preferred Term	Produ	uot.	Comp.	OTC	Role	Route	Dosage	a Tavt	Duration	<u>M</u> 1	-



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Device Failure	Epipe	en Auto-Injector			S		0.3 Mg, Prn		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083301	NON-EXPEDITED				US-MYLAN 2015M1007	_		Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Incorrect Rou Of Drug Administration	ıte	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083306	NON-EXPEDITED				US-MYLAN 2015M1007		5 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Accidental Exposure T Product By Child; Expi Product Administered		en Auto-Injector			S		0.3 Mg, Once		Му	⁄lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u> Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083310	NON-EXPEDITED				US-MYLAN 2015M1009	_	3 YR	Female	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Injed Site Swelling		en Auto-Injector			S		0.3 Unk, Once		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083311	NON-EXPEDITED				US-MYLAN 2015M1008			Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Device Failure; Expired Product Administered	d Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg Once		Му	<b>r</b> lan



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							-				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083314	NON-EXPEDITED				US-MYL 2015M1	ANLABS- 005807		25 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered		n Auto-Injector			S		0.3	Mg, Unk		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083316	NON-EXPEDITED				US-MYL 2015M1	ANLABS- 005422		26 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered; Headac Injection Site Bruising	uct Imitre	n Auto-Injector x /01044801/			S C	Oral		, Once Mg, Prn			ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083317	NON-EXPEDITED				US-MYL 2015M1	ANLABS- 002958		52 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered; Injection Site Discolouration; Injection Site Haemorrhage; Injectio Site Hypoaesthesia; Injection Site Pain; Injection Site Swelling Palpitations; Tremor	uct Epiper n	n Auto-Injector n Auto-Injector			S S		0.3	Mg, Prn			ylan ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083318	NON-EXPEDITED				US-MYL 2015M1	ANLABS- 014595		62 YR	Female	USA



Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mf	r
Accidental Exposure T Product; Injection Site Coldness; Injection Site Pain	luct; Injection Site ness; Injection Site				S		0.15	/lg, Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083323	NON-EXPEDITED				US-MYLA 2015M10				Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Injection Site Injury	o Epipe	n Jr. Auto-Injector			S		Unk, (	Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083343	NON-EXPEDITED				US-MYLA 2015M10				Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		М	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083344	NON-EXPEDITED				US-MYLA 2015M10	_			Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>M</u> f	<u>r</u>
Accidental Exposure T Product	o Epipe	n Auto-Injector			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083346	NON-EXPEDITED				US-MYLA 2015M10				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>M</u> f	<u>r</u>
Product Storage Error	Enine	n Auto-Injector			S		Unk			M	ylan

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Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12083348	NON-EXPEDITED					-		71 YR	Female	USA
Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
ed; Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	rlan
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12083350	EXPEDITED (15-DAY)		0	T		-			Female	USA
Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Epipen	Auto-Injector			S		Unk			Му	rlan
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12083352	EXPEDITED (15-DAY)		0	T					Male	USA
Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Epipen	Auto-Injector			S		Unk			Му	rlan
Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12083353	NON-EXPEDITED					-			Female	USA
Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	e Text	<u>Duration</u>	Mfr	
Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	rlan
Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12083355	NON-EXPEDITED				US-MYLANI 2015M1018				Male	USA
	Produce Epipen  Case # 12083350  Produce Epipen  Case # 12083352  Produce Epipen  Case # 12083353  Produce Epipen  Case #	Product Epipen Auto-Injector  Case # Case Type 12083350 EXPEDITED (15-DAY)  Product Epipen Auto-Injector  Case # Case Type 12083352 EXPEDITED (15-DAY)  Product Epipen Auto-Injector  Case # Case Type 12083353 NON-EXPEDITED  Product Epipen Auto-Injector  Case # Case Type 12083353 NON-EXPEDITED  Product Epipen Auto-Injector  Case # Case Type 12083353 NON-EXPEDITED	Product Case # Case Type Health 12083350 EXPEDITED (15-DAY)  Product Case # Case Type Health 12083350 EXPEDITED (15-DAY)  Product Case # Case Type Health 12083352 EXPEDITED (15-DAY)  Product Comp. Epipen Auto-Injector  Case # Case Type Health 12083353 NON-EXPEDITED  Product Case # Case Type Health 12083353 NON-EXPEDITED  Product Case # Case Type Health 12083353 NON-EXPEDITED  Product Case # Case Type Health 12083353 NON-EXPEDITED	Product Comp. OTC  Epipen Auto-Injector  Case # Case Type Health Prof Off  Product Comp. OTC  Epipen Auto-Injector  Case # Case Type Health Prof Off  Epipen Auto-Injector  Case # Case Type Health Prof Off  Epipen Auto-Injector  Product Comp. OTC  Epipen Auto-Injector  Case # Case Type Health Prof Off  Epipen Auto-Injector  Case # Case Type Health Prof Off  Epipen Auto-Injector  Case # Case Type Health Prof Off  Epipen Auto-Injector  Case # Case Type Health Prof Off  Epipen Auto-Injector  Case # Case Type Health Prof Off  Epipen Auto-Injector	Product Comp. OTC Role  Case # Case Type Health Prof Outcomes  12083350 EXPEDITED (15-DAY)  Product Comp. OTC Role  Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes  12083352 EXPEDITED (15-DAY)  OT  Product Comp. OTC Role  Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes  12083352 EXPEDITED (15-DAY)  Product Comp. OTC Role  Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes  12083353 NON-EXPEDITED  Product Comp. OTC Role  Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes  12083353 NON-EXPEDITED  Product Comp. OTC Role  Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes	Product Case # Case Type Health Prof Outcomes Mfr Control Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes S  Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes S  Expedited (15-DAY) OT Role Route  Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes Mfr Control Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes Mfr Control Epipen Auto-Injector S  Case # Case Type Health Prof Outcomes S  Intramuscular  Case # Case Type Health Prof Outcomes Mfr Control Epipen Auto-Injector S  Intramuscular  Case # Case Type Health Prof Outcomes Mfr Control US-MYLANI 2015M10186  Case # Case Type Health Prof Outcomes Mfr Control US-MYLANI 20263355 NON-EXPEDITED US-MYLANI 20263355 NON-EXPEDITED US-MYLANI 20263355 US-MYL	Description   Product   Product	Product Comp. OTC Role Route Dosage Text    Case # Case Type	12083348   NON-EXPEDITED	Product Comp. OTC Role Route Dosage Text Duration Mfr  Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex  Product Comp. OTC Role Route Dosage Text Duration Mfr  Epipen Auto-Injector S Intramuscular 0.3 Mg, Once Mg  Case # Case Type Health Prof Outcomes Duration Mfr  Epipen Auto-Injector S Unk Mg  Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex  Product Comp. OTC Role Route Dosage Text Duration Mfr  Epipen Auto-Injector S Unk Mg  Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Mg  Epipen Auto-Injector S Unk Mg  Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Mg  Epipen Auto-Injector S Unk Duration Mfr  Epipen Auto-Injector S Unk Duration Mfr  Epipen Auto-Injector S Intramuscular 0.3 Mg, Once Mg  Case # Case Type Health Prof Outcomes Outcom



Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	•
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Once		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol # 503B Fac	ility Age	<u>Sex</u>	Country
17-Feb-2016	12083356	NON-EXPEDITED				US-MYLA 2015M102	_	52 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure	Epipe	n Auto-Injector			S		Unk, Once		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol # 503B Fac	ility Age	<u>Sex</u>	Country
17-Feb-2016	12083357	NON-EXPEDITED				US-MYLA 2015M101	_	64 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol # 503B Fac	ility Age	<u>Sex</u>	Country
17-Feb-2016	12083358	NON-EXPEDITED				US-MYLA 2015M101			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mfr	
Injection Site Laceration	on Epipe	n Auto-Injector			S		Unk		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol # 503B Fac	<u>ility</u> <u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083363	NON-EXPEDITED				US-MYLA 2015M102		55 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	•
Accidental Exposure T Product; Expired Prod Administered; Heart R Increased; Injection Site Bruising; Injection Site Discolouration; Injection Site Swelling	uct ate ite	n Auto-Injector			S	Intramuscular	0.3 Mg, Once		Му	/lan

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FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083364	NON-EXPEDITED				US-MYLAN 2015M101	_		2 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>otc</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	:
Accidental Exposure T Product By Child; Injec Site Discolouration		n Auto-Injector			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	12083365	NON-EXPEDITED				US-MYLAN 2015M101				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product By Child; Injec Site Bruising; Injection Erythema	ction	n Auto-Injector			S	Intramuscular	0.3 M	lg, Prn		Му	vlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083367	NON-EXPEDITED				US-MYLAN 2015M101				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	lg, Prn		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083371	NON-EXPEDITED				US-MYLAN 2015M101	-		31 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure; Injection Site Bruising	on Epipe	n Auto-Injector			S	Intramuscular	0.3 M	lg, Prn	Mylan		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083372	NON-EXPEDITED				US-MYLAN 2015M101	_			Male	USA



Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	M	<u>lfr</u>
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Ņ	Mylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083375	NON-EXPEDITED				US-MYLA 2015M102			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Device Failure	Epipe	n Auto-Injector			S		Unk, Once		N	Mylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083379	NON-EXPEDITED				US-MYLA 2015M102		4 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Accidental Exposure T Product By Child; Expi Product Administered; Injection Site Coldness Injection Site Injury	ired	n Jr. Auto-Injector			S		Unk		N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
17-Feb-2016	12083380	NON-EXPEDITED				US-MYLA 2015M10			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Device Failure; Incorre Dose Administered By Device		n Auto-Injector			S		Unk		N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083382	NON-EXPEDITED				US-MYLA 2015M10		8 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
	Accidental Exposure To Epipen Auto-Injector Product By Child; Expired				S		Unk, Once		N	Mylan

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Product Administered;

Injection Site

Haemorrhage; Injection

Site Injury

Site Injury											
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083383	NON-EXPEDITED				US-MYLAN 2015M102				Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	Mfr	
Injection Site Laceration	on Epipe	en Auto-Injector			S		Unk,	Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083386	NON-EXPEDITED				US-MYLAN 2015M102	-			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 N	/lg, Prn		Му	rlan e
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083387	NON-EXPEDITED				US-MYLAN 2015M101	-			Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product	o Epipe	en Auto-Injector			S		Once	)		Му	rlan e
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083391	NON-EXPEDITED				US-MYLAN 2015M101	-		29 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T		en Jr. Auto-Injector			S		Unk,	Once		Му	rlan
Product; Expired Prod Administered; Injection Site Pain; Injection Site Pallor; Maternal Expos During Pregnancy	n iloli e				С		Unk			Му	rlan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083392	NON-EXPEDITED				US-MYLAN 2015M102	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	Mf	<u>r</u>
Device Failure; Drug Ineffective; Oxygen Saturation Decreased	Epipe	en Auto-Injector			S		0.3 N	Mg, Once		M	ylan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	12083396	NON-EXPEDITED				US-MYLAN 2015M102	-			Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mf	<u>r</u>
Device Failure	Epipe	en Auto-Injector			S		0.3 N	/Ig, Once		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof 9	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083398	NON-EXPEDITED				US-MYLAN 2015M102	-		65 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	<u>Dosag</u>	ge Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Injection Site Bruising; Injection Site Haemorrhage; Injection Site Hypoaesthesia; Skeletal Injury	Epipe	en Auto-Injector en Auto-Injector			S S		Unk	Unk, Once			ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083404	NON-EXPEDITED				US-MYLAN 2015M102	_		42 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Feeling Jittery Injection Site Haemorrhage		en Jr. Auto-Injector raceptives			S C	Intramuscular 0.15 Mg, Once Unk				ylan ylan	



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083408	NON-EXPEDITED				US-MYLAN 2015M1024	=	46 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	
Accidental Exposure T Product; Injection Site Hypoaesthesia; Injecti Site Pain; Musculoske Stiffness	on Clarit	en Auto-Injector in /00413701/			S C		0.3 Mg, Once			/lan /lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083419	NON-EXPEDITED				US-MYLAN 2015M1017		20 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	:
Injury Associated With Device	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Once		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083431	NON-EXPEDITED				US-MYLAN 2015M1018			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	:
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 Unk, Unk		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083433	NON-EXPEDITED				US-MYLAN 2015M1020		6 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	:
Accidental Exposure T Product By Child; Inject Site Erythema; Injection Site Injury; Injection Si Pallor	ction on	en Jr. Auto-Injector			S	Subcutaneous	Unk, Once		My	/lan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083480	NON-EXPEDITED				US-MYLAN 2015M1027	_		60 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Expired Product Administered	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083481	NON-EXPEDITED				US-MYLAN 2015M1028	_			Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S		Unk,	Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083482	NON-EXPEDITED				US-MYLAN 2015M1028				Female	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S		0.3 M	g, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083484	NON-EXPEDITED				US-MYLAN 2015M1026			67 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; No Adverse Event	ō Epipe	n Auto-Injector			S	Intramuscular	Unk,	Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083486	NON-EXPEDITED				US-MYLAN 2015M1028	_			Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Device Failure	Epipe	en Auto-Injector	S 0.3 Mg, Onc  Health Prof Outcomes Mfr Control # 503							M	lylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083487	NON-EXPEDITED				US-MYLAN 2015M1026	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		М	lylan
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083490	NON-EXPEDITED				US-MYLAN 2015M1028			1 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Device Failure	Epipe	en Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Prn		М	lylan
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083491	NON-EXPEDITED				US-MYLAN 2015M1028				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>M</u> f	<u>ir</u>
Accidental Exposure 1 Product	o Epipe	en Jr. Auto-Injector			S		Unk,	Once		M	lylan
FDA Received Date	Case #	Case Type	Health	Prof O	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083498	NON-EXPEDITED				US-MYLAN 2015M1025			17 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; No Adverse Event	ō Epipe	en Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		M	lylan
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083499	NON-EXPEDITED				US-MYLAN 2015M1027				Female	USA



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Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Dispensing Error	- Epipe	en Auto-Injector			S		Unk		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof O	<u>Outcomes</u>	Mfr Conti	ol # 503B Fa	<u>cility</u> <u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083500	NON-EXPEDITED				US-MYLAN 2015M102			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipe	en Jr. Auto-Injector			S		Unk		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>Outcomes</u>	Mfr Conti	ol # 503B Fa	<u>cility</u> <u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083524	NON-EXPEDITED				US-MYLAN 2015M103		4 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child	o Epipe	en Jr. Auto-Injector			S		0.15 Mg, Once		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>Outcomes</u>	Mfr Cont	<u>503B Fa</u>	<u>cility</u> <u>Age</u>	<u>Sex</u>	<b>Country</b>
17-Feb-2016	12083527	NON-EXPEDITED				US-MYLAN 2015M102			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>Dutcomes</u>	Mfr Cont	ol # 503B Fa	<u>cility</u> <u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083535	NON-EXPEDITED				US-MYLAN 2015M104			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof O	<u> Dutcomes</u>	Mfr Conti	ol # 503B Fa	cility Age	<u>Sex</u>	Country
17-Feb-2016	12083536	NON-EXPEDITED				US-MYLAN 2015M102			Female	USA



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<u>Preferred Term</u>	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Contusion	Epipe	n Trainer			S		Unk			My	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083538	NON-EXPEDITED				US-MYLAN 2015M103				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Pain In Extremity	Epipe	n Trainer			S		Unk			My	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083541	NON-EXPEDITED				US-MYLAN 2015M104				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	ı, Prn		My	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083546	NON-EXPEDITED				US-MYLAN 2015M102				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Injection Site Hypoaesthesia	o Epipe	n Auto-Injector			S		Unk, C	nce		My	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083552	NON-EXPEDITED				US-MYLAN 2015M103			51 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	ı, Once		My	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083557	NON-EXPEDITED		US-MYLANLABS- 2015M1034713						Female	USA



Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mf</u>	r
Accidental Exposure T Product; Skeletal Injur		en Auto-Injector			S		Unk,	Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083560	NON-EXPEDITED				US-MYLAN 2015M103	-			Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mf</u>	<u>'r</u>
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	Unk	Unk, Once		М	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083561	NON-EXPEDITED				US-MYLAN 2014M100	-		1 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Device Failure; Injection Site Laceration; Injection Site Scar		en Jr. Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083564	NON-EXPEDITED				US-MYLAN 2015M103				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>ge Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Feeling Jittery; Palpitations	Epipe	en Auto-Injector			S	Intramuscular	0.3 M	lg, Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083565	NON-EXPEDITED				US-MYLAN 2015M103	-		4 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product By Child	o Epipe	en Jr. Auto-Injector			S		Unk	Unk, Once		M	ylan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083573	NON-EXPEDITED				US-MYLANI 2015M1044			45 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product; Expired Product; Administered; Heart Ra Increased; Injection Sit Hypoaesthesia; Injection Site Pain; Injection Site Paraesthesia; Injection Site Swelling	uct ate te on	n Jr. Auto-Injector			S		0.15 Mç	g, Unk		Ν	/Iylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083574	NON-EXPEDITED				US-MYLANI 2015M1028	_			Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product	o Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg,	Once		N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083575	NON-EXPEDITED				US-MYLANI 2015M1046			79 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product; Expired Produ Administered; Heart Ra Increased	uct	n Auto-Injector			S	Intramuscular	0.3 Mg,	Prn		N	<b>1</b> ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083576	NON-EXPEDITED				US-MYLANI 2015M1032			8 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage</b>	<u>Text</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>
Drug Dispensing Error	Epipe	n Auto-Injector			S	Unk			Mylan		

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FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083580	NON-EXPEDITED				US-MYLAI 2015M103				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipe	en Auto-Injector			S		Unk L	Jnk, Once		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083581	NON-EXPEDITED				US-MYLAN 2014M100			1 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Laceration Injection Site Scar; Injudential State State Injudential Injudential Injection Site of Injection State Injection Sta	ury	en Jr. Auto-Injector			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083583	NON-EXPEDITED				US-MYLAI 2015M103				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083584	NON-EXPEDITED				US-MYLAI 2015M102				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Pain; Unevaluable Eve	ent Epipe	en Trainer			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083585	NON-EXPEDITED				US-MYLAI 2015M103	-			Female	USA
Preferred Term	Prod	uet	Comp.	OTC	Role	Route	Dosag	o Toyt	Duration	Mfr	



Malaise; Nausea	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Once			Mylan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083589	NON-EXPEDITED				US-MYLANL 2015M10458	_		5 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Accidental Exposure T Product By Child	o Epipe	n Jr. Auto-Injector			S		1 Df, 0	Once			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083592	NON-EXPEDITED				US-MYLANL 2015M10307				Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Heart Rate Increased	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Once			Mylan
	Metop	orolol Tartrate			С	Oral	10 Mg	ı, Bid			Mylan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083593	NON-EXPEDITED				US-MYLANL 2014M10033			11 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Injection Site Laceration	on Epipe	n Auto-Injector			S		Unk				Mylan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083596	NON-EXPEDITED				US-MYLANL 2015M10313				Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>		<u>Mfr</u>
Accidental Exposure T Product	o Epipe	n Auto-Injector			S		Unk				Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083597	NON-EXPEDITED				US-MYLANL 2015M10356			2 YR	Male	USA

**Date - Time: 15-May-2018 01:32:07 PM EST** Note

Note: If the field is blank, there is no data.

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Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Injection Site Laceration	on Epipe	n Jr. Auto-Injector			S		Unk		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083598	NON-EXPEDITED				US-MYLAN 2015M1035		3 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Injection Site Laceration Injection Site Scar	on; Epipe	n Jr. Auto-Injector			S		Unk		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083603	NON-EXPEDITED				US-MYLAN 2015M1037	_		Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	:
Hypersensitivity	Epipe	n Auto-Injector			S	Intramuscular	Unk Unk, Prn		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083606	NON-EXPEDITED				US-MYLAN 2015M1041	_		Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	:
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Once		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083609	NON-EXPEDITED				US-MYLAN 2015M1044			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	:
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Unk		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083611	NON-EXPEDITED				US-MYLAN 2015M1029			Female	USA



Preferred Term	Product	1	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Expired Produ Administered		Auto-Injector			S		Unk Unk, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083614	NON-EXPEDITED				US-MYLAN 2015M1040		5 YR	Female	USA
Preferred Term	Product	<u>I</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Accidental Exposure To Product By Child; Injec Site Pain		Auto-Injector			S	Intramuscular	Unk, Once		My	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2016	12083757	EXPEDITED (15-DAY)		C	DT	NL-MYLAN 2016M1007			Unknown	NLD
Preferred Term	Product	<u>I</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure	Epipen				S				Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Feb-2016	12103083	EXPEDITED (15-DAY)		C	DΤ	FR-MYLAN 2016M1007			Unknown	FRA
Preferred Term	Product	<u>I</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Drug Ineffective; Produ Quality Issue	ıct Epipen				S	Intramuscular			My	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Feb-2016	12111061	DIRECT		L	.T			21 YR	Female	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Needle Issue; Product Leakage					S		0.3 Mg, As Needed, Into The Muscle 15 Seconds		My	an
,	Junel				С					



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

								Detailed	iveboir				
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Intramuscular Duration Mfr  Product Comp. OTC Role Route Dosage Text Duration Mfr  Intramuscular Duration Mfr  Mylan Duration Mfr  Product Comp. OTC Role Route Dosage Text Duration Mfr  Mylan Duration Mfr  Mylan Duration Mfr  Product Comp. OTC Role Route Dosage Text Duration Mfr  Product Pish Oil Stephen Auto-Injector South Residency South Re			Prednisor Benadryl				C C						
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr    Product Comp. OTC Role Route Dosage Text Duration Mfr	FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Epipen 0.3 Mg Mylan Inc.   S   Intramuscular   C   C	24-Feb-2016	121150°	13	DIRECT			LT				20 YR	Female	USA
Addininstered By Device; Cymbalta Fish Oil  Cymbalta Fish Control # Soas Facility Age Sex Country  Cymbalta Fish Oil  Cymbalta	Preferred Term		Product		Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
1208348   NON-EXPEDITED   US-MYLANLABS-2015M1026217   67 YR   Female   USA	Injection Site Extravasation; Needle	e;	Cymbalta	-			С	Intramuscular				Му	rlan
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Orug Effect Decreased; Epipen Auto-Injector S Intramuscular 0.3 Mg, Once Mylan Product Administered; Atenolol S Oral 50 Mg, Bid  Oral 75 Mg, Once Mylan Premor; Vomiting Benadryl /00000402/ Seroquel C C Oral 200 Mg, Hs Mylan  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  Oreferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Device Failure Epipen Jr S Mg/An  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  Orl-Mar-2016 12131370 EXPEDITED (15-DAY) OT NIL-MYLANLABS-  Oral 50 Mg, Bid  Oral 75 Mg, Once Mylan  Oral 200 Mg, Hs Mylan  Mfr Control # 503B Facility Age Sex Country  Oral 200 Mg, Hs Outender Dosage Text Duration Mfr  Overice Failure Epipen Jr S Mg/An  Oral 200 Mg, Hs Outender Dosage Text Duration Mfr  Mylan  Oral 200 Mg, Hs Outender Dosage Text Duration Mfr  Mylan  Oral 200 Mg, Hs Outender Dosage Text Duration Mfr  NL-MYLANLABS- Unknown NLD	FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
Product Administered; Atenolol S Oral 50 Mg, Bid Atenolol S Oral 50 Mg, Bid Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral 75 Mg, Once Mylan  Atenolol S Oral S Ora	29-Feb-2016	1208348	88	NON-EXPEDITED							67 YR	Female	USA
Atenolol S Oral 50 Mg, Bid Atenolol S Oral 50 Mg, Bid Atenolol S Oral 75 Mg, Once Mylan Benadryl /00000402/ S Oral 75 Mg, Once Mylan Seroquel C Oral 200 Mg, Hs Mylan  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  O1-Mar-2016 12131368 EXPEDITED (15-DAY) OT Role Route Dosage Text Duration Mfr  Device Failure Epipen Jr S Mgr Control # 503B Facility Age Sex Country  D1-Mar-2016 12131370 EXPEDITED (15-DAY) OT NL-MYLANLABS- D1-Mar-2016 Unknown NLD	Preferred Term		<u>Product</u>		Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
FDA Received Date   Sample   S	Product Administered;	ed	Atenolol	uto-Injector			S			_		Му	rlan
Seroquel C Oral 200 Mg, Hs Mylan  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  D1-Mar-2016 12131368 EXPEDITED (15-DAY) OT NL-MYLANLABS-2016M1009087  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Device Failure Epipen Jr S Mylan  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  D1-Mar-2016 12131370 EXPEDITED (15-DAY) OT NL-MYLANLABS-  Unknown NLD		١,		/0000402/			S	Oral	75 Mc	n Once		Му	rlan
O1-Mar-2016 12131368 EXPEDITED (15-DAY) OT NL-MYLANLABS-2016M1009087 Unknown NLD  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Device Failure Epipen Jr S Mylan  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  O1-Mar-2016 12131370 EXPEDITED (15-DAY) OT NL-MYLANLABS- Unknown NLD	. ,		-						_			•	
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Device Failure Epipen Jr S Mylan  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  O1-Mar-2016 12131370 EXPEDITED (15-DAY) OT NL-MYLANLABS- Unknown NLD	FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Device Failure Epipen Jr S Mylan  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  01-Mar-2016 12131370 EXPEDITED (15-DAY) OT NL-MYLANLABS- Unknown NLD	01-Mar-2016	1213136	68	EXPEDITED (15-DAY)			ОТ					Unknown	NLD
FDA Received Date	Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
D1-Mar-2016 12131370 EXPEDITED (15-DAY) OT NL-MYLANLABS- Unknown NLD	Device Failure		Epipen Jr				S					Му	rlan
01-Mar-2016 12131370 EXPEDITED (15-DAY) OT NL-MYLANLABS- Unknown NLD 2016M1009065	FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	01-Mar-2016	1213137	70	EXPEDITED (15-DAY)	) OT NL-MYLANLABS-						Unknown	NLD	

Note: If the field is blank, there is no data.

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Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Device Failure		ı (Epinephrine) Auto r 0.3 Mg			S		1mg/1ml		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol # 503B Fa	cility Age	<u>Sex</u>	Country
01-Mar-2016	12131371	EXPEDITED (15-DAY)		Н	)	GB-MYLAN 2016M100	_		Unknown	GBR
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Asthenia; Drug Ineffec Myalgia	tive; Epiper	1			S				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol # 503B Fa	cility Age	<u>Sex</u>	Country
01-Mar-2016	12131374	EXPEDITED (15-DAY)		0	Г	NL-MYLAN 2016M100			Unknown	NLD
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Device Failure		ı (Epinephrine) Auto r 0.3 Mg			S				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol # 503B Fa	cility Age	<u>Sex</u>	Country
01-Mar-2016	12133156	EXPEDITED (15-DAY)		Н	)	GB-MYLAN 2016M100			Unknown	GBR
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Compartment Syndron Injection Site Pain	ne; Epiper	1			S				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol # 503B Fa	cility Age	<u>Sex</u>	Country
01-Mar-2016	12133343	EXPEDITED (15-DAY)		0	Γ	US-MYLAN 2016M100			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Injury Associated With Device	ed With Epipen Auto-Injector				S	Intramuscular	0.3 Mg, Prn		Му	lan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Mar-2016	12137091	DIRECT		Н	O, LT, OT				35 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Chest Discomfort; Dyspnoea Fear	Epipen Epipen a; Iron				S C C						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Mar-2016	12077238	EXPEDITED (15-DAY)		Lī	г, от	US-MYLAN 2016M1005				Unknown	USA
Preferred Term	Produc	<u>ot</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Device Failure; Drug	Epipen	Auto-Injector			S	Intramuscular	0.3 M	lg, Inject Prn		Му	lan
Effect Incomplete	Insulin	Detemir			С		Unk				
	Insulin A	Aspart			С		Unk				
	Fluticas	sone			С		Unk				
	Lorazep	pam			С		Unk				
	Levothy	yroxine			С		Unk				
	Montelu	ukast			С		Unk				
	Simvas	tatin			С		Unk				
	Hydroc	odone			С		Unk				
	Cyclobe	enzaprine Hydrochloride			С		Unk				
	Pantopi Sesquil	razole Sodium			С		Unk				
	Trazodo				С		Unk				
	Metforn	nin			С		Unk				
	Lisinopril			С		Unk					
	Hydroxyzine				С		Unk				
	Prednis	sone			С		Unk				



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Mar-2016	12171134	EXPEDITED (15-DAY)		0	Γ	GB-MYLANLABS- 2016M1010730				Unknown	GBR
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	Mfr	
Device Failure	Epipe	en			S					Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Mar-2016	11990404	EXPEDITED (15-DAY)		Н	O, OT	US-MED 1047217	TRONIC-		11 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<b>Duration</b>	Mfr	
Device Breakage; Hiccups; Hypertonia;	Inject				S	Intrathecal				Мє	edtronic
Medical Device Site Fibrosis; Muscle	Baclo				S	Oral					
Tightness; Therapeuti Response Decreased	Qvai	erol azepam			S S S	Oral					
		en Gum Packet otrigine			S S S	Oral					
	Lamo	otrigine			S	Oral					
	Lanso	oprazole			S	Oral					
	Levet Lidoc	iracetam aine			S S	Topical					
		nex (Mometasone Furoate			S	·					
	Monohydrate) Multivitimin With Iron (Tab-A-V W/Iron)	/itimin With Iron (Tab-A-Vite n)			S	Oral					
	•	ga-3s/Dha/Epa/Fish Oil			S	Oral					
		odone Hydchloride ethylene Glycol 2250			S S	Oral					
		ım Citrate And Citric Acid amate			S S						



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex Country	E
23-Mar-2016	12083915	EXPEDITED (15-DAY)			HO, OT	PHHY2016US	014941		Male USA	
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Hiccups; Hypertonia; Medical Device Site	Liores	sal Intratecal			S	Intrathecal	50.04 Ug, Qd Concentration 500 Mcg/M	l		
Fibrosis; Muscle Tightness; Therapeutic Response Decreased	Liores Baclo	sal Intratecal fen			S S	Oral	40 Mg, Qd (In Divided Doses)			
	Clona	azepam			S	Unknown	0.125 Mg, Disintegrating Tablet		Novartis	
	Albut	erol			S	Unknown	2.5mg/3ml (0.083%) Neb Solution			
		methasone//Beclometason ropionate			S	Unknown	80 Ug, Actuation Inhaler			
	Epipe				S	Unknown	0.3mg/0.3ml (1:1,000)			
	Guar	Gum			S	Unknown				
	Lacto	bacillus Acidophilus			S	Unknown				
	Lamid	ctal			S	Unknown	100 Mg, Unk			
	Lamid	ctal			S	Unknown	25 Mg, Unk			
	Preva	acid			S	Unknown	15 Mg, Unk			
	Kepp	ra			S	Unknown				
	Emla	/01389401/			S	Unknown				
	Tab A	Vite + Iron			S	Unknown				
	Naso	nex			S	Unknown				
	Ome	ga 3 Complex /08219501/			S	Oral				
	Roxic	codone			S	Unknown				
	Polye	ethylene Glycol			S	Unknown				
	Oraci	t			S	Unknown	490-640mg			
	Topa	max			S	Unknown	15 Mg, Unk			



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Mar-2016	12208566	EXPEDITED (15-DAY)		F	Ю	US-MYLAN 2016M101				Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Cont	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Apr-2016	12229753	EXPEDITED (15-DAY)		[	DE, OT	AU-MYLAN 2016M101				Unknown	AUS
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Anaphylactic Shock; Dineffective	rug Epipen Epipen				S S		Unk			Myl Myl	
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Cont	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Apr-2016	12233097	EXPEDITED (15-DAY)		C	T	US-MYLAN 2016M101	_			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipen	Jr. Auto-Injector			S	Intramuscular	0.15 N	/lg, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Cont	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Apr-2016	12247119	EXPEDITED (15-DAY)		C	T	DE-MYLAN 2016M101	_			Unknown	DEU
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Expired Prod Administered; Injection Site Hypoaesthesia; Injection Site Pallor; Needle Issue; Occupational Exposur Product; Skin Injury	uct				S					Myl	an



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	#	503B Facility	Age	Sex	Country
14-Apr-2016	12270455	DIRECT	Hounn	1101	<u>Jatoomico</u>	<u> </u>	<u></u>	<u>ocob i domity</u>	4 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Injec Site Haemorrhage; Injection Site Pallor; Injection Site Pallor; In Associated With Devic	iury	Jr			S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12273448	EXPEDITED (15-DAY)		H	НО	US-MYLANLA 2016M101477				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Apr-2016	12297349	EXPEDITED (15-DAY)		(	OT	US-MYLANLA 2016M101612	_			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Apr-2016	12320382	EXPEDITED (15-DAY)		(	OT	US-MYLANLA 2016M101686	_			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipen	Jr. Auto-Injector			S	Intramuscular	Unk, P	?rn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-May-2016	12335081	EXPEDITED (15-DAY)		(	OT	FR-MYLANLA 2016M101806				Unknown	FRA



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Administration Site Ischaemia; Medication		en			S	Intramuscular	Daily Dose: 1 Df Dosage Form Every Days		My	lan
Error; Wrong Technique Product Usage Proces		cade			С	Oral			My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-May-2016	12335090	EXPEDITED (15-DAY)		C	DΤ	BE-MYLAN 2016M1018			Unknown	BEL
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure; Injectic Site Bruising		en (Epinephrine) Auto or 0.3 Mg			S				My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12335143	EXPEDITED (15-DAY)		C	T	US-MYLAN 2016M1017			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure; Wrong Technique In Product Usage Process	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Once		My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2016	12366066	EXPEDITED (15-DAY)		C	T	US-ENDO PHARMACI INC2016-0		58 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Lip Swelling; Urticaria	Hydro	ocortisone Tablets			S	Unknown				
	Epipe	en			S	Unknown				
	Zanta	C			S	Unknown				
	Bena	dryl			S	Unknown				
	Prednisone				S	Unknown				



							100011				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-May-2016	12368986	EXPEDITED (15-DAY)		0	Γ	US-MYLANL 2016M10192	_			Unknown	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Asthenia; Drug Effect Incomplete; Somnolen Tremor		n Auto-Injector n Auto-Injector			s s	Intramuscular Intramuscular	0.3 Mg 0.3 Mg	g, Once g, Prn		Myli Myli	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-May-2016	12375548	EXPEDITED (15-DAY)		0	Γ	JP-TEVA-20 001065J	16-JP-			Unknown	JPN
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Anaphylactic Reaction Drug Ineffective	; Doxaz Epiper	osin Tablet 4mg "Teva" n			s s	Oral Unknown					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2016	12380824	EXPEDITED (15-DAY)		0	Γ	US-MYLANL 2016M10194	-			Unknown	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mç	g, Once		Myla	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2016	12387522	EXPEDITED (15-DAY)		0	Γ	US-MYLANL 2016M10201	-			Unknown	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Myla	an
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u># lc</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-May-2016	12388509	EXPEDITED (15-DAY)		Н	)	JP-MYLANL 2016M10209				Unknown	JPN



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Gait Disturbance	Epipen				S	Intramuscular	Unk, S	ingle		Му	an
	Epipen				S			_		Му	
	Saxizon				S	Intravenous drip	300 Mg	g, Daily		My	
	Polaram	nine			S	Intravenous drip	5 Mg, [	Daily		My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
23-May-2016	12393989	EXPEDITED (15-DAY)		D	E	GB-MYLANLA 2016M102099				Unknown	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Anaphylactic Shock;	Epipen				S		Unk			My	lan
Arthropod Sting; Drug Ineffective	Epipen				S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-May-2016	12395485	EXPEDITED (15-DAY)		C	T	US-MYLANLA 2016M101673	_			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	Mfr	
Device Failure; Intentio Product Misuse	onal Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2016	12412212	EXPEDITED (15-DAY)		C	T	HR-MYLANLA 2016M102218	-			Unknown	HRV
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	Mfr	
Accidental Exposure To Product; Injection Site Discolouration; Injectio Site Swelling					S					Му	an
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-May-2016	12413400	EXPEDITED (15-DAY)		C	T	US-MYLANLA 2016M102115	-			Unknown	USA
Preferred Term	Produc	+	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	Mfr	



						Dotalioa No	Port			
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2016	12425806	EXPEDITED (15-DAY)			DE	CA-PFIZER INC K200601089	>-	61 YR	Male	CAN
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Anaphylactic Shock; Angioedema; Cardio- Respiratory Arrest; Dru Ineffective; Drug Interaction; Dyspnoea; Vomiting	Accup	essor			s s C		0.3 Mg, Single 100 Mg, 2x/Day 20 Mg, 1x/Day		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2016	12428399	DIRECT			LT			7 YR	Male	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Device Malfunction; Laceration; Medical Device Site Haemorrha Medical Device Site Inj Needle Issue; Scratch	Speci age; Epipe	erol With Chamber iins			s C C C C	Intramuscular	1 Injection (S) As Needed Into The Muscle		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jun-2016	12436148	EXPEDITED (15-DAY)			ОТ	US-MYLANLAB 2016M1021909	_		Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Injection Site Laceratio	n Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15 Mg, Prn		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2016	12131372	EXPEDITED (15-DAY)			НО	SE-MYLANLAB 2016M1009056			Unknown	SWE
Preferred Term	Prod	uet	Comp.	отс	Role	Route	Dosage Text	Duration	Mf	



Device Failure		Epipen (Epinephrine) Auto Injector 0.3 Mg			S				Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2016	121799	21 EXPEDITED (15-DAY	<b>'</b> )		LT	SE-MYLANLA 2016M101107			Unknown	SWE
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure; Expired Device Used	d	Epipen			S				Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jun-2016	123528	86 NON-EXPEDITED			ОТ	US-MDT-ADR 00495	-2016-	38 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Hypertonia; Muscle		Lioresal			S	Intrathecal	134.3 Mcg/Day.			
Spasms; Pain In Extre	mity	Azelastine			S	Nasal	137 Mcg			
		Epipen			S		·			
		Fluticasone			S	Nasal	50 Mcg/Actuation			
		Gabapentin			S	Oral				
		Norco			S	Oral	5-325 Mg			
		Levothyroxine			S	Oral				
		Montelukast			S	Oral				
		Lioresal			S	Intrathecal	122.12 Mcg/Day			
		Advil Pm			S	Oral				
		Albuterol			S	Respiratory (inhalation)	90 Mcg/Actuatlon			
		Citalopram			S	Oral				
		Simvastatin			S	Oral				
		Loratadine			S	Oral	One Tablet As Needed			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2016	124722	53 EXPEDITED (15-DAY	<b>'</b> )		ОТ	US-PFIZER IN	IC-	87 YR	Female	USA



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2016290452

Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	Mfr	
Drug Ineffective; Feelir Abnormal; Lethargy; Li Discomfort					S S	Intramuscular Intramuscular	0.3 Mg	ı, 3x ı, Once		Pfiz Pfiz	
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jun-2016	12486631	NON-EXPEDITED				US-PFIZER IN 2016307187	C-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injury Associa With Device					S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2016	12490245	EXPEDITED (15-DAY)		ŀ	НО	US-MYLANLA 2016M102500				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Hospitalisation	Epipen .	Jr. Auto-Injector			S	Intramuscular	0.15 M	lg, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jun-2016	12486332	EXPEDITED (15-DAY)		ŀ	HO, OT	US-PFIZER IN 2016307524	C-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective; Dyspnoea; Headache; Swelling	Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jun-2016	12500547	NON-EXPEDITED				US-PFIZER IN 2016317774	C-		5 YR	Female	USA



Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Bruising; Product Quality Issue	Epipen .	Jr			S	Intramuscular	0.15 Mg, Prn		Pfiz	er
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof (	<u>Outcomes</u>	Mfr Contr	ol # 503B Fa	acility Age	<u>Sex</u>	Country
01-Jul-2016	12497333	EXPEDITED (15-DAY)		I	DE	US-MYLAN 2016M1026			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Drug Dose Omission	Epipen .	Jr. Auto-Injector			S		Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol # 503B Fa	acility Age	<u>Sex</u>	Country
01-Jul-2016	12522417	EXPEDITED (15-DAY)		I	HO, OT	GB-MYLAN 2016M1027			Unknown	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Wrong Techn In Product Usage Proc	ique				S				Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol # 503B Fa	acility Age	<u>Sex</u>	Country
01-Jul-2016	12522549	EXPEDITED (15-DAY)		(	ОТ	US-MYLAN 2016M1026	_		Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen .	Auto-Injector			S		0.3 Mg, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol # 503B Fa	acility Age	<u>Sex</u>	Country
06-Jul-2016	12465525	NON-EXPEDITED				US-PFIZER 201629087	_	65 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Expired Product; Administered; Injection Site Bruising; Injection Coldness; Injection Site	ict Site	0.3mg			S		0.3 Mg, Injection	n	Pfiz	er

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.

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Hypoaesthesia; Injection Site Injury; Injection Site Pain; Injection Site Swelling; Pain In Extremity; Palpitations; Poor Quality Drug Administered; Product Quality Issue

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2016	12531387	EXPEDITED (15-DAY)		0.	Т	BE-PFIZE 20162482	-		19 YR	Female	BEL
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ige Text	<b>Duration</b>	Mfr	
Injection Site Bruising; Product Quality Issue	Epipe	n Jr			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2016	12531750	NON-EXPEDITED				US-PFIZI 20163283	-		6 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	<u>ige Text</u>	<u>Duration</u>	Mfr	:
Accidental Exposure T Product By Child; Injec Site Bruising; Injection Haemorrhage; Tremor	ction Site	n Jr			S		0.15	5 Mg, Unk		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
07-Jul-2016	12208563	EXPEDITED (15-DAY)		Н	O, OT	US-MYLA 2016M10	_			Unknown	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosa	<u>ige Text</u>	<u>Duration</u>	Mfr	:
Accidental Exposure T Product; Arthritis; Inject Limb Mobility Decrease Injection Site Pain; Injection Site Pallor; Wrong Technique In Product Usage Proces	cted ed;	n Auto-Injector			S		Unk			Му	<i>r</i> lan



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
07-Jul-2016	12535940	EXPEDITED (15-DAY)			ОТ	US-AST 2016SE	RAZENECA- 72332			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling; Pharynge Oedema; Swollen Ton		Otc			S S	Oral Unknown				Ast	razeneca
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2016	12537619	NON-EXPEDITED			ОТ	US-PFI 201632	ZER INC- 8555		33 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hypersensitivity; React To Excipient	tion Epipen	c/00011701/			s s c		0.3 Mg Unk	g, As Needed (Prn)		Pfiz Pfiz	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jul-2016	12540461	NON-EXPEDITED				US-PFI 201633	ZER INC- 4535			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Epipen Aspirin				s s		Unk Unk			Un	known
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	entrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2016	12393263	EXPEDITED (15-DAY)			ОТ		_ANLABS- 021175			Unknown	FRA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Discolouration; Injectio Site Pain; Injury Associated With Devic	Injector n	(Epinephrine) Auto 0.3 Mg			S					Му	lan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2016	12506011	EXPEDITED (15-DAY)		Ľ	Т	CZ-MYLANL 2016M10268				Unknown	CZE
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure; Loss C Consciousness	of Epipen				S			Dose: 1 Df Dosage Every Days		M	ylan
	Prednis	olone			С	Oral	1 Df, 0	Qd		M	ylan
	Zyrtec				С	Oral	2 Df, 0	Qd		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2016	12545319	EXPEDITED (15-DAY)		0	т	US-PFIZER 2016176437				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Injection Site Joint Inflammation; Injection Site Movemel Impairment; Injection S Pain; Injection Site Pal Wrong Technique In Product Usage Proces	nt Site Ior;	Jr			S		0.3 M	g, Unk		Pi	iizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jul-2016	12546436	EXPEDITED (15-DAY)		0	Τ	GB-PFIZER 2016339001	-			Female	GBR
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Anxiety; Perinatal Depression	Epipen				S		Unk			Pi	izer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2016	12548229	NON-EXPEDITED				US-PFIZER 2016337447				Unknown	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>



Epipen

## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bone Contusion; Gait Disturbance; Injection Site Bruising; Injection Site Discomfort; Injection Site Haematoma; Injection Site

Unk

Pfizer

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	<u> # lo</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
12-Jul-2016	12550557	NON-EXPEDITED				US-PFIZER 2016337552	-			Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mfı</u>	:
Euphoric Mood	Epipen				S	Unknown	Unk			Pf	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2016	12545198	NON-EXPEDITED				US-PFIZER 2016337611			65 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>otc</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mfı</u>	:
Accidental Exposure T Product; Expired Product; Expired; Heart Rancreased; Injection Site Coldness; Injection Site Hypoaesthesia; Injection Site Injury; Injection Site Pain; Injection Site Swelling; Pain In Extremity; Palpitations Product Colour Issue; Product Expiration Dat Issue	uct ate te ee on te				S		0.31	Mg, Unk			zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jul-2016	12561349	EXPEDITED (15-DAY)		(	DΤ	FR-PFIZER 2016275509	-		33 YR	Female	FRA

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## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Accidental Exposure To Product; Injection Site Discolouration; Injection Site Injury; Injection Site Epipen Jr S

Unk

Pfizer

FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	Sex	Country
15-Jul-2016	12563089	EXPEDITED (15-DAY)		0		US-MYLANI 2016M1028	LABS-			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Device Failure; Expired Product Administered	d Epipen	Auto-Injector			S	Intramuscular	0.3 M	g, Once		My	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2016	12570370	NON-EXPEDITED				US-PFIZER 2016347929				Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T					S		Unk			Pfiz	er
Pain; Wrong Techniqu	e In										
Pain; Wrong Techniqu Product Usage Proces	e In ss	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro		503B Facility	<u>Age</u>	<u>Sex</u>	Country
Pain; Wrong Techniqu Product Usage Proces FDA Received Date	e In ss	Case Type EXPEDITED (15-DAY)	<u>Health</u>	Prof O	_	Mfr Contro US-MYLANI 2016M1029	<b>ol #</b> LABS-	503B Facility	<u>Age</u>	<u>Sex</u> Unknown	<b>Country</b> USA
Product; Injection Site Pain; Wrong Techniqu Product Usage Proces  FDA Received Date  20-Jul-2016  Preferred Term	e In ss <u>Case #</u>	EXPEDITED (15-DAY)	Health Comp.		_	US-MYLANI	<b>ol #</b> LABS-		Age  Duration		
Pain; Wrong Techniqu Product Usage Proces  FDA Received Date  20-Jul-2016  Preferred Term  Accidental Exposure T Product; Injection Site Hypoaesthesia; Injectic	Case # 12577017  Production  Epipen on	EXPEDITED (15-DAY)		0	Т	US-MYLANI 2016M1029	<b>DI #</b> LABS- 017		_	Unknown	USA
Pain; Wrong Technique Product Usage Proces  FDA Received Date  20-Jul-2016  Preferred Term  Accidental Exposure Toroduct; Injection Site Hypoaesthesia; Injection Site Swelling; Palpitation	Case # 12577017  Production  To Epipen  on ons	EXPEDITED (15-DAY)		OTC	T Role	US-MYLANI 2016M1029	ol# LABS- 017 Dosag Unk		_	Unknown <u>Mfr</u>	USA
Pain; Wrong Techniqu Product Usage Proces FDA Received Date 20-Jul-2016	Case # 12577017  Production  To Epipen  on ons	EXPEDITED (15-DAY)  Et  Jr. Auto-Injector	Comp.	OTC Prof O	Role S	US-MYLANI 2016M1029 Route	DI#  LABS- 017  Dosage  Unk  DI#  LABS-	e Text	<u>Duration</u>	Unknown <u>Mfr</u> Myl	USA an



Coma; Death	Epipen				S		Unk				Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2016	12580952	EXPEDITED (15-DAY)			НО	JP-TEVA-201 001605J	6-JP-		15 YR	Male	JPN
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	ļ	<u>Mfr</u>
Gait Disturbance		n For Intravenous			S	Intravenous drip	300 Mil	ligram Daily;			Teva
	Epipen	n 1000mg			S	Intramuscular					
	Epipen Polara				S S	Intravenous drip	5 Millig	ram Daily;			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2016	12580980	EXPEDITED (15-DAY)			ОТ	US-MYLANL/ 2016M10291				Unknow	n USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	ļ	<u>Mfr</u>
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	, Unk			Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jul-2016	12581021	EXPEDITED (15-DAY)			ОТ	US-MYLANL/ 2016M10291	-			Unknow	n USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	ļ	<u>Mfr</u>
Device Failure	Epipen	Auto-Injector			S		Unk				Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	#	503B Facility	<u>Age</u>	Sex	Country
25-Jul-2016	12587793	EXPEDITED (15-DAY)			DE, HO	AU-PFIZER I 2016357522	NC-		15 YR	Male	AUS
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	ļ	<u>Mfr</u>
Coma; Death	Epipen				S		Unk				Pfizer



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date	ontrol # 503B Facility Age Sex Country
25-Jul-2016 12588138 NON-EXPEDITED US-PFIZ 2016357	ZER INC- Female USA 7196
Preferred Term Product Comp. OTC Role Route	<u>Dosage Text</u> <u>Duration</u> <u>Mfr</u>
Accidental Exposure To Epipen S Product; Injection Site Pain; Wrong Technique In Product Usage Process	Unk(0.3mg 2 Pack) Pfizer
FDA Received Date	ntrol # 503B Facility Age Sex Country
25-Jul-2016 12589726 EXPEDITED (15-DAY) OT US-PFIZ 2016356	ZER INC- Male USA 6021
<u>Preferred Term</u> <u>Product</u> <u>Comp. OTC</u> <u>Role</u> <u>Route</u>	<u>Dosage Text</u> <u>Duration</u> <u>Mfr</u>
Accidental Exposure To Epipen Jr S Product; Injection Site Hypoaesthesia; Injection Site Swelling; Palpitations	Unk Pfizer
FDA Received Date	ontrol # 503B Facility Age Sex Country
26-Jul-2016 12596526 EXPEDITED (15-DAY) OT US-PFIZ 2016361	ZER INC- 59 YR Female USA 1177
Preferred Term Product Comp. OTC Role Route	Dosage Text Duration Mfr
Condition Aggravated; Epipen S Intramuscular	r 0.3 Mg, Unk Pfizer
Hypersensitivity; Reaction Metformin C To Excipient; Respiratory	Unk
Distress Armour Thyroid C	Unk
Epinephrine /00003902/ C	Unk, As Needed
FDA Received Date	ontrol # 503B Facility Age Sex Country
27-Jul-2016 12596195 EXPEDITED (15-DAY) OT US-BAX 2016BAX	KTER- X038208 Female USA
Preferred Term Product Comp. OTC Role Route	Dosage Text Duration Mfr
Fluid Overload; Meningitis 0.9% Sodium Chloride Injection S Unknown	Baxter



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Aseptic	Chloride Injection Usp				S	Unknown				Bax	xter
	Hepar	de Injection Usp in Sodium In 0.9% Sodium de Injection			S	Unknown	Stre	ngth: 10 lu/Ml		Bax	xter
	Ampyr				S	Oral					
	Gamm	nagard Liquid			S	Parenteral	Via I	Infusion			
	Acetar	minophen			S	Unknown					
	Dipher	nhydramine Hydrochloride			S	Unknown					
	Epiper	ı			S	Unknown					
	Zoloft				S	Unknown					
	Vitami	n D3			S	Unknown					
	Copax	one			S	Unknown					
	Ortho	Tri-Cyclen			S	Unknown					
	Spiron	olactone			S	Unknown					
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2016	12606731	EXPEDITED (15-DAY)			НО	GB-MYLAN 2016M1031				Unknown	GBR
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mfr	
Dyspnoea; Headache; Loss Of Consciousnes Malaise		1			S					Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2016	12607522	EXPEDITED (15-DAY)			ОТ	CA-MYLAN 2014M1008				Unknown	CAN
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	<u>Role</u>	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site Ischaemia		1			S		Unk	Unk, Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2016	12608575	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2016M1030	-			Unknown	USA

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.



Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen /	Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Myl	an
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2016	12613663	DIRECT							3 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Laceration; Needle Iss	ue; Epi Pen	Jr			S	Intramuscular					
Product Quality Issue	Singulai Calcium	r Supplement			C C						
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2016	12608581	EXPEDITED (15-DAY)		I	_T, OT	US-MYLANLA 2016M103008	-			Unknown	USA
Preferred Term	<u>Produc</u>	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective; Injecti Site Swelling	ion Epipen <i>i</i>	Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2016	12614824	EXPEDITED (15-DAY)		(	TC	US-PFIZER IN 2016368339	IC-			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Finger Amputation; Skeletal Injury; Wrong Techniqu In Product Usage Prod	ue				S		Unk, Or	nce		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2016	12611438	EXPEDITED (15-DAY)		I	_T, OT	US-PFIZER IN 2016368608	IC-		73 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	Mfr	



Drug Ineffective; Injection Site Swelling	ion Epipen				S	Intramuscular	0.3 M	g, Once		Р	fizer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2016	12618545	EXPEDITED (15-DAY)			НО	GB-PFIZER 2016368219			25 YR	Female	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Dyspnoea; Headache; Loss Of Consciousness Malaise	Epipen s;				S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Aug-2016	12626642	EXPEDITED (15-DAY)			ОТ	US-PFIZER 2014363426				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injectio Site Ischaemia; Injectio	o Epipen				S		Unk			Р	fizer
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injectio Site Ischaemia; Injectio	o Epipen on	Case Type	Health	Prof	S Outcomes	Mfr Contro		503B Facility	Age	Sex	fizer <u>Country</u>
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injectio Site Ischaemia; Injectio Site Pallor	o Epipen on	Case Type NON-EXPEDITED	<u>Health</u>	Prof		Mfr Contro US-PFIZER 2016375541	ol # INC-	503B Facility	<u>Age</u>		
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Ischaemia; Injection Site Pallor  FDA Received Date 08-Aug-2016	Epipen on Case #	NON-EXPEDITED	Health Comp.	Prof OTC	<u>Outcomes</u>	US-PFIZER	ol # INC-		Age Duration	Sex	<u>Country</u> USA
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injectio Site Ischaemia; Injectio Site Pallor FDA Received Date	Case # 12633765	NON-EXPEDITED			<u>Outcomes</u>	US-PFIZER 2016375541	ol # INC-			Sex Female	<u>Country</u> USA
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Ischaemia; Injection Site Pallor  FDA Received Date  08-Aug-2016  Preferred Term  Pain	Case # 12633765  Product	NON-EXPEDITED	Comp.	отс	Outcomes Role	US-PFIZER 2016375541 Route	ol # INC- Dosage Unk			Sex Female	Country USA fr
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Ischaemia; Injection Site Pallor  FDA Received Date  08-Aug-2016  Preferred Term  Pain	Case # 12633765  Product Epipen	NON-EXPEDITED	Comp.	OTC Prof	Outcomes  Role S	US-PFIZER 2016375541 Route Unknown	Dosage Unk Di#	e Text	<u>Duration</u>	Sex Female M	Country USA  fr
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Site Ischaemia; Injection Site Pallor  FDA Received Date 08-Aug-2016  Preferred Term  Pain	Case #  12633765  Product Epipen Case #	NON-EXPEDITED  It  Case Type  EXPEDITED (15-DAY)	Comp.	OTC Prof	Outcomes  Role S Outcomes OT	US-PFIZER 2016375541  Route  Unknown  Mfr Contro	Dosage Unk Di#	503B Facility	<u>Duration</u>	Sex Female Mi	Country USA  fr  fizer  Country CAN



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Aug-2016	12635871	NON-EXPEDITED				US-PFIZER IN 2016377284	IC-		3 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Psychomotor Hyperact		Jr			S		0.15 M	lg, Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Aug-2016	12635888	NON-EXPEDITED				US-PFIZER IN 2016377282	IC-		5 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product By Child; Injec Site Injury		0.3mg			S		Unk, C	)nce		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Aug-2016	12640373	DIRECT	Υ							Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Packaging Confusion	Epipen				S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Aug-2016	12641984	EXPEDITED (15-DAY)		С	T	US-MYLANLA 2016M103244	-			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	յ, Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Aug-2016	12522422	EXPEDITED (15-DAY)		н	IO, OT	FR-MYLANLA	RC.			Unknown	FRA



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Preferred Term	ed Term Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug Ineffective; Loss Of	sthma; Device Defective; device Failure; Drug deffective; Loss Of consciousness; Oxygen				S	Intramuscular	0.15mg, Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Aug-2016	12647290	DIRECT		0	Г			51 YR	Female	CHE
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Product Formulation Is		n 0.3 Mg Epinephrine Injector			S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Aug-2016	12648788	NON-EXPEDITED				US-PFIZER 201638322	=	63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prodi Administered; Injectior Site Pain; Wrong Technique In Product Usage Process	uct	n Jr			S		Unk, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Aug-2016	12602830	EXPEDITED (15-DAY)		0	Γ	JP-PFIZER 201635504		3 YR	Unknown	JPN
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Injection Site Discolouration; Injection Site Injury; Injection Site Ischaemi Injection Site Swelling	etion	n 0.15mg			S	Intramuscular	Unk		Pfiz	zer

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FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Aug-2016	12653030	NON-EXPEDITED				US-PFIZER 2016384984	-			Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Extremity; Prod Administered At Inappropriate Site	duct Epip	en			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Aug-2016	12655783	NON-EXPEDITED				US-PFIZER 2016384981	-		3 YR	Unknown	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Injury; Product Quality Issue	Epip	en Jr			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Aug-2016	12655884	NON-EXPEDITED				US-PFIZER 2016386595			5 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injury	Epip	en			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	Age	<u>Sex</u>	Country
18-Aug-2016	12665592	EXPEDITED (15-DAY)		Н	O, OT	US-MYLAN 2016M1034				Unknown	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increa		en Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
Device Failure; Heart I Increased; Underdose		ofen			С		Unk			Му	lan
54554, 5114614656	Ben	adryl /00000402/			С		Unk			Му	lan
	Pep	cid /00305201/			С		Unk			Му	lan
					С					My	



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Aug-2016	12667405	NON-EXPEDITED				US-PFIZEF 201639192				Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mf	<u>r</u>
Pain	Epipen				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Aug-2016	12668833	EXPEDITED (15-DAY)		Lī	Γ	AU-MYLAN 2016M1034				Unknown	AUS
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mf	<u>.</u>
Drug Ineffective; Liquio Product Physical Issue		Jr Adrenaline Auto- r			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Aug-2016	12471715	EXPEDITED (15-DAY)		0	Т	US-PFIZEF 201629963			5 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mf	<u>.</u>
Accidental Exposure T Product; Heart Rate Increased; Limb Injury Nail Injury; Oxygen Saturation Decreased					S		0.3 M	g, Once		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Aug-2016	12680263	EXPEDITED (15-DAY)		H	O, OT	US-PFIZEF 201639589			34 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	e Text	<u>Duration</u>	Mf	<u>.</u>
Blood Pressure Increa					S	Intramuscular	0.3 M	g, Once		Pf	izer
Heart Rate Increased; Product Quality Issue;		en			С		Unk				
Underdose	Benad	ryl /00000402/			С		Unk				
0114014000											



	Bisopr	olol			С		Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Aug-2016	12683646	NON-EXPEDITED				US-PFIZ 2016397				Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Expired Prod Administered; Injection Site Laceration	uct	n Jr			S		Unk	, Once		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2016	12689498	EXPEDITED (15-DAY)		0	Γ	NL-MYL 2016M10	ANLABS- 036288			Unknown	NLD
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mf	<u>r</u>
Drug Administration E	Deslor Diclofe Panta	zol < /00068001/			S C C C C	Topical				M M M M	ylan ylan ylan ylan ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
26-Aug-2016	12692681	DIRECT	Y	DS	3				49 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	<u>Route</u>	<u>Dosa</u>	ge Text	<u>Duration</u>	Mf	<u>r</u>
Device Issue	Epiper	1			S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Co	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2016	12692701	DIRECT							22 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mf</u>	r
Device Malfunction; Laceration; Needle Iss	Epiper sue;	1			S						

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Treatment Failure											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Aug-2016	12697887	NON-EXPEDITED				US-PFIZE 201640680	-			Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site Erythema; Injection Sit Haemorrhage		ı			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Aug-2016	12699112	EXPEDITED (15-DAY)		(	ЭТ	US-MYLAI 2016M103				Unknown	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Aug-2016	12699955	EXPEDITED (15-DAY)		(	TC	US-MYLAI 2016M103	-			Unknown	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Expire	d Epiper	n Jr. Auto-Injector			S	Intramuscular	0.15 N	lg, Prn		Му	lan
Product Administered	Epiper	n Jr. Auto-Injector			S	Intramuscular		lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Aug-2016	12701170	DIRECT							59 YR	Male	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Product Expiration Dat Issue; Product Label Confusion	Enbrel Citalop Loraze	oram			S C C C						



	Mart) Hydroxy	/zine			С						
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	<u>Mf</u>	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Aug-2016	12667347	EXPEDITED (15-DAY)		(	TC		i-JAZZ-2016-US- 5124			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mf</u>	:
Drug Abuse; Psychotic	C Xyrem				S	Oral	2.25	G, Bid		Ja	ZZ
Disorder	Xyrem				S	Oral	Dose	Adjustments		Ja	zz
	Xyrem				S	Oral	4.5 G	i, Bid		Ja	zz
	Dextroa	mphetamine			S		Unk				
	Epipen Nuvigil				S C		Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mf	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Aug-2016	12704334	NON-EXPEDITED					-PFIZER INC- 16408677			Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	
Injection Site Bruising	Epipen				S		Unk			Pf	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mf	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Sep-2016	12706488	NON-EXPEDITED		(	TC		-PFIZER INC- 16406312			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	•
Drug Ineffective	Epipen				S	Intramus	cular 0.3 M	lg, As Needed, Prn		Pf	zer
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mf	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Sep-2016	12707720	NON-EXPEDITED					-PFIZER INC- 16412688			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	:

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FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Sep-2016	12712514	NON-EXPEDITED		C	T	US-PFIZER 2016412670			56 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen				S	Intramuscular	0.3 Mg	g, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contro	ol#	503B Facility	Age	<u>Sex</u>	Country
06-Sep-2016	12711772	NON-EXPEDITED				US-PFIZER 2016412684				Female	USA
Preferred Term	Produc	<u>!</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Screen False Positive	Epipen				S		0.3 Mg	յ, Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Sep-2016	12717349	DIRECT	Υ	L	.Т					Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Drug Ineffective; Inject Site Haemorrhage	tion Epipen (	0.3% Mylan			S	Intramuscular				Му	lan
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Sep-2016	12717783	EXPEDITED (15-DAY)		C	T	FI-MYLANL 2016M1037				Unknown	FIN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen				S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2016	12717926	NON-EXPEDITED		C	DΤ	US-PFIZER 2016416659	-		82 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # <u>503B Fa</u>	cility Age	<u>Sex</u>	Country
07-Sep-2016	12721806	EXPEDITED (15-DAY)		0	Γ	US-MYLAN 2016M1037			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Anaphylactic Reaction; Device Failu		n Auto-Injector			S		0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Fa	cility Age	<u>Sex</u>	Country
07-Sep-2016	12722434	EXPEDITED (15-DAY)		0	Γ	US-MYLAN 2016M1037	_		Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Expired Product Administered	d Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Fa	cility Age	<u>Sex</u>	Country
07-Sep-2016	12722445	EXPEDITED (15-DAY)		0	Γ	US-MYLAN 2016M1037			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Expired Product Administered; Injury Associated With Devic Loss Of Consciousnes Skeletal Injury	e;	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Fa	cility Age	<u>Sex</u>	Country
08-Sep-2016	12728949	DIRECT		Н	)			79 YR	Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Device Malfunction		n. Lot #6gmo71 Mylan			S		Other Strength:;0 Dose:;Other Frequency:;Othe Route:Injection F	r	Му	lan
	Citalo	pram			С					



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	Amlodip	pine			С						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
09-Sep-2016	12717354	NON-EXPEDITED				US-PFIZER 2016401205				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Drug Hypersensitivity	Epipen Proair				s s		Unk Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof Ou	tcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Sep-2016	12728885	NON-EXPEDITED		ОТ	-	US-PFIZER 2016422511			29 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Drug Ineffecti Product Quality Issue					S		0.3 Mg	g, Prn		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Sep-2016	12730229	EXPEDITED (15-DAY)		ОТ	-	US-MYLANL 2016M10377				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	:
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof Ou	tcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Sep-2016	12735476	EXPEDITED (15-DAY)		ОТ	-	US-PFIZER 2016422509			63 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	e Text	<b>Duration</b>	Mfr	
Drug Administration Er Expired Product Administered; Foreign Body; Loss Of Consciousness; Produ Quality Issue; Skeletal	ıct				S	Intramuscular	0.3 M <sub>(</sub>	g, Prn		Pfi	zer



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Injury											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Sep-2016	12736050	EXPEDITED (15-DAY)		C	T	JP-PFIZER I 2016420884			75 YR	Female	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Malaise; Seizure	Epipen				S	Intramuscular	Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Sep-2016	12739036	EXPEDITED (15-DAY)		H	lO, OT	US-MYLANL 2016M10377				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Inject Site Haemorrhage	tion Epipen /	Auto-Injector			S	Intramuscular	0.3 M	g, Twice		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Sep-2016	12737085	EXPEDITED (15-DAY)		C	T	JP-MYLANL 2016M10391	-			Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Malaise; Seizure	Epipen				S	Intramuscular	Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Sep-2016	12743346	EXPEDITED (15-DAY)		F	Ю	US-MYLANL 2016M10380				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D Omission	Dose Epipen /	Auto-Injector			S	Intramuscular	Use A	As Directed, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Sep-2016	12708614	EXPEDITED (15-DAY)		C	T	US-MYLANL 2016M10364				Unknown	USA



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Produc	t	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Chest Discomfort; Devi Failure; Feeling Abnorr Injection Site Injury		Auto-Injector			S	Intramuscular	Unk			Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Sep-2016	12746043	EXPEDITED (15-DAY)		H	HO, OT	US-PFIZER 2016429353				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Injecti Site Haemorrhage	ion Epipen	Jr			S	Intramuscular	0.3 Mg	g, Twice		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Sep-2016	12726043	EXPEDITED (15-DAY)		(	T	NL-MYLANL 2016M10379				Unknown	NLD
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Hypoaesthesi Injection Site Coldness Injection Site Pallor; Product Administered A Inappropriate Site; Vasoconstriction	ia;	Auto-Injector			S	Subcutaneous	Single	e Administration		МуІ	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Sep-2016	12749648	EXPEDITED (15-DAY)		C	DΤ	FR-MYLANI 2016M1039				Unknown	FRA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen				S	Subcutaneous	0.3 Mg	g/MI, Unk		Myl	lan
	Epipen				S	Subcutaneous		g/Ml, Unk		Myl	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Sep-2016	12749653	EXPEDITED (15-DAY)		[	DE	GB-MYLANI 2016M1039				Unknown	GBR



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Produc	t	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Cardiac Arrest	Epipen				S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	Sex	Country
20-Sep-2016	12717793	EXPEDITED (15-DAY)		C	T	US-PFIZER II 2016415040	NC-		22 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	Mfr	:
Chest Discomfort; Fee Abnormal; Injection Sit Injury; Product Quality Issue; Underdose	te <sub>Eninen</sub>				S S	Intramuscular	Unk				zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2016	12729201	EXPEDITED (15-DAY)		C	T	NL-PFIZER IN 2016425566	NC-		79 YR	Female	NLD
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	Mfr	:
Accidental Exposure T Product; Hypoaesthes Injection Site Coldness Injection Site Pallor; Product Administered Inappropriate Site; Vasoconstriction; Wrot Technique In Product Usage Process	ia; s; At				S	Subcutaneous	0.3 MI,	Single		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2016	12761708	NON-EXPEDITED				US-PFIZER II 2016438077	NC-			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	Mfr	:
Nausea	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	<u>utcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2016	12762531	EXPEDITED (15-DAY)		D	E, OT	GB-PFIZER II	NC-		11 YR	Male	GBR

Note: If the field is blank, there is no data.

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2016437505

Preferred Term	Produc	<u>t</u>	Comp.	OTC		Route	Dosage	e Text	<u>Duration</u>	<u>M1</u>	_
Cardiac Arrest; Drug Ineffective	Epipen				S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2016	12764304	NON-EXPEDITED				US-PFIZER 201643744	-		38 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product; Injection Site Discolouration; Injectio Site Hypoaesthesia; Intentional Product Mis	on				S	Intramuscular	0.3 Mg	g, Prn		Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2016	12764337	NON-EXPEDITED				US-PFIZER 201643807			50 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>M1</u>	<u>ir</u>
Accidental Exposure T Product; Expired Produ Administered; Injection Site Pain	uct				S	Intramuscular	0.3 Mg	g, Prn		Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2016	12764569	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2016M1039				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>M1</u>	<u>ir</u>
Device Failure	Epipen /	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		M	lylan



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Sep-2016	12769100	EXPEDITED (15-DAY)		C	DΤ	DK-MYLAN 2016M103				Unknown	DNK
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Administration Site Pain		n			S					Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Sep-2016	12769102	EXPEDITED (15-DAY)		L	.T	DK-MYLAN 2016M103				Unknown	DNK
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Conti	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Sep-2016	12773352	EXPEDITED (15-DAY)		(	TC	US-MYLAN 2016M103	-			Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Sep-2016	12236297	NON-EXPEDITED				US-PFIZEF 201619189	-		58 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Lip Swelling; Urticaria;	Epipe	n			S		Unk			Pfi	zer
Wrong Technique In Product Usage Proces	Cortis	one			S		Unk			Pfi	zer
	Benad	dryl			S		Unk				
	Predn	isone			S		Unk				
	Zanta	С			S		Unk				



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2016	12563097	EXPEDITED (15-DAY)		(	OT	FR-MYLAN 2016M1029				Unknown	FRA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure; Needle Issue	Aerius /	Auto-Injector 01009701/ d /00016201/			S C C		0.15 N Unk Unk	lg, Unk		Му	lan lan lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2016	12780331	EXPEDITED (15-DAY)		(	OT	DK-PFIZEF 201643860				Female	DNK
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure To Product; Injection Site Pain	o Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2016	12781427	NON-EXPEDITED				US-PFIZEF 201644889				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Intentional Product Misuse; Palpitations	Epipen				S		0.3 Mg	g, Unk		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Sep-2016	12784177	NON-EXPEDITED				US-PFIZEF 201644888			50 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure To Product; Anxiety; Tachycardia	o Epipen				S	Intramuscular	0.3 Mg	g, Prn		Pfi	zer



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pain In Extremity Epiper S Unk Pfizer  FDA Received Date Case # Case Type Health Prof Outcomes US-PFIZER INC-2016412683  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Epiper Jr S Unk Pfizer INC-2016412683  Pfizer S Unk Pfizer INC-2016412683  Unk Preferred Term Product; Dizziness; Espired Product; Dizziness; Injection Site Pain Product Administered; Injection Site Pain Product Administered; Injection Site Pain Product Dizziness; Injection Site Pain Dizziness;												
Preferred Term	FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Faligue   Epipen   S	30-Sep-2016	12687761	NON-EXPEDITED								Unknown	USA
FDA Received Date   Case   Froduct   Comp.   Mon-EXPEDITED   Solutions   Mon-EXPEDITED   Solutions	Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
03-Oct-2016 12693869 NON-EXPEDITED	Fatigue	Epipen				S		Unk			Pfiz	zer
Preferred Term	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Pain In Extremity Epipen S Unk Pfizer  FDA Received Date Case # Case Type Health Prof Outcomes US-PFIZER INC-2016412683  O3-Oct-2016 12707261 NON-EXPEDITED	03-Oct-2016	12693869	NON-EXPEDITED								Unknown	USA
FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Country    03-Oct-2016   12707261   NON-EXPEDITED	Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
O3-Oct-2016 12707261 NON-EXPEDITED  Preferred Term  Product Comp. OTC Role Route Dosage Text Duration Mfr  Accidental Exposure To Epipen Jr FDA Received Date 12718023 NON-EXPEDITED  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Pfizer  S Unk Pfizer  S Unk Pfizer  Product Site Haemorrhage; Injection Site Pain  FDA Received Date 12718023 NON-EXPEDITED  TOT US-PFIZER INC- 2016416658  19 YR Male USA  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Product Product S Unk Pfizer  Product Product S US-PFIZER INC- 2016416658  19 YR Male USA  Preferred Term Product Epipen S Unk Pfizer  Product S Unk Pfizer  Product V US-PFIZER INC- 2016416658  19 YR Male USA  Preferred Term Product S Unk Pfizer  Product V US-PFIZER INC- 2016416658  19 YR Male USA  Preferred Term Doug Ineffective Epipen WFr Unk V US-MYLANLABS- V Unk V US-MYLANLABS- V Unknown USA	Pain In Extremity	Epipen				S		Unk			Pfiz	zer
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Accidental Exposure To Epipen Jr S Unk Pfizer  Product; Dizziness; Expired Product Administered; Injection Site Pain  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  03-Oct-2016 12718023 NON-EXPEDITED OT US-PFIZER INC-2016416658  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Drug Ineffective Epipen S Unk Pfizer  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  US-PFIZER INC-2016416658  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Drug Ineffective Epipen S Unk Pfizer  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  03-Oct-2016 12790036 EXPEDITED (15-DAY) HO US-MYLANLABS- Unknown USA	FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Accidental Exposure To Product; Dizziness; Expired Product Administered; Injection Site Pain  FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Country    03-Oct-2016   12718023   NON-EXPEDITED   OT   US-PFIZER INC-2016416658    Preferred Term   Product   Comp.   OTC   Role   Route   Dosage Text   Duration   Mfr    Drug Ineffective   Epipen   S   Unk   Pfizer    FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Country    Drug Ineffective   Epipen   S   Unk   Pfizer    FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Country    03-Oct-2016   12790036   EXPEDITED (15-DAY)   HO   US-MYLANLABS-   Unknown   USA	03-Oct-2016	12707261	NON-EXPEDITED								Unknown	USA
Product; Dizziness; Expired Product Administered; Injection Site Haemorrhage; Injection Site Pain    FDA Received Date   Case #   Case Type   Health Prof   Outcomes   Mfr Control #   503B Facility   Age   Sex   Country	Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
03-Oct-2016 12718023 NON-EXPEDITED OT US-PFIZER INC-2016416658  Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr  Drug Ineffective Epipen S Unk Pfizer  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  03-Oct-2016 12790036 EXPEDITED (15-DAY) HO US-MYLANLABS- Unknown USA	Product; Dizziness; Expired Product Administered; Injectior Site Haemorrhage;		Jr			S		Unk			Pfiz	zer
Preferred Term         Product         Comp.         OTC         Role         Route         Dosage Text         Duration         Mfr           Drug Ineffective         Epipen         S         Unk         Pfizer           FDA Received Date         Case #         Case Type         Health Prof         Outcomes         Mfr Control #         503B Facility         Age         Sex         Country           03-Oct-2016         12790036         EXPEDITED (15-DAY)         HO         US-MYLANLABS-         Unknown         USA	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Drug Ineffective Epipen S Unk Pfizer  FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country  03-Oct-2016 12790036 EXPEDITED (15-DAY) HO US-MYLANLABS- Unknown USA	03-Oct-2016	12718023	NON-EXPEDITED		(	OT				19 YR	Male	USA
FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 03-Oct-2016 12790036 EXPEDITED (15-DAY) HO US-MYLANLABS- Unknown USA	Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
03-Oct-2016 12790036 EXPEDITED (15-DAY) HO US-MYLANLABS- Unknown USA	Drug Ineffective	Epipen				S		Unk			Pfiz	zer
	FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol #	503B Facility	Age	Sex	Country
	03-Oct-2016	12790036	EXPEDITED (15-DAY)		ŀ	НО					Unknown	USA



Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Oct-2016	12823676	EXPEDITED (15-DAY)		(	T	NL-MYLAN 2016M1042			Unknown	NLD
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure	Epipen				S				Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Oct-2016	12824238	NON-EXPEDITED				US-PFIZEF 201619463		48 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Feeling Jittery Palpitations		Jr			S	Intramuscular	Unk, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Oct-2016	12825754	DIRECT						2 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Dispensing Error	Epipen	Jr			S		Quantity:2 Injection(S);		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2016	12838627	EXPEDITED (15-DAY)		C	T	US-MYLAN 2016M1042	_		Unknown	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Produ Administered; No Adve Event	uct	Jr. Auto-Injector			S		Unk		Му	lan



FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2016	12838633	EXPEDITED (15-DAY)		0	Γ	CZ-MYLAN 2016M1043	_			Unknown	CZE
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n			S		0.3 Mg	g, Unk		My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2016	12841563	EXPEDITED (15-DAY)		0	Γ	US-MYLAN 2016M1043				Unknown	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug D Omission	ose Epipe	n Auto-Injector			S		Unk			My	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Oct-2016	12844739	NON-EXPEDITED				US-PFIZER 201647785				Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Expired Product; Administered		n Jr			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Oct-2016	12844867	EXPEDITED (15-DAY)		0	Γ	US-MYLAN 2016M1043	-			Unknown	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Hypoaesthesia; Wrong Technique In Product Usage Process		n Auto-Injector			S	Intramuscular	0.3 M <u>(</u>	g, Once		Myl	lan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Oct-2016	12847631	NON-EXPEDITED				US-PFIZER IN 2016479656	NC-		3 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product By Child; Injec Site Discolouration; Injection Site Pain		en Jr			S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Oct-2016	12849520	EXPEDITED (15-DAY)		(	OT	US-PFIZER II 2016479657	NC-		81 YR	Male	USA
Preferred Term	Proc	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Accidental Exposure T Product; Injection Site		en			S	Intramuscular	0.3 Mg	g, Once		Р	fizer
Hypoaesthesia; Wrong Technique In Product Usage Process											
Technique In Product	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	#	503B Facility	Age	<u>Sex</u>	Country
Technique In Product Usage Process  FDA Received Date		Case Type EXPEDITED (15-DAY)	Health		Outcomes DE	Mfr Control CA-PAR PHARMACEL COMPANIES 2016SCPR01	JTICAL -	503B Facility	Age	<u>Sex</u> Unknown	<u>Country</u> CAN
Technique In Product Usage Process  FDA Received Date 19-Oct-2016	Case # 12860481		Health Comp.			CA-PAR PHARMACEL COMPANIES	JTICAL -	•	Age Duration		CAN
Technique In Product Usage Process  FDA Received Date 19-Oct-2016  Preferred Term  Cardiac Arrest; Drug D	Case # 12860481  Proc	EXPEDITED (15-DAY)		[	DE	CA-PAR PHARMACEL COMPANIES 2016SCPR01	JTICAL - 5998 <u>Dosage</u>	•	-	Unknown Mt	CAN
Technique In Product Usage Process  FDA Received Date 19-Oct-2016  Preferred Term	Case # 12860481  Proc Oose Adre	EXPEDITED (15-DAY)		[	DE <u>Role</u>	CA-PAR PHARMACEL COMPANIES 2016SCPR01	JTICAL - 5998 <b>Dosage</b> Unk U	e Text	-	Unknown Mt	CAN
Technique In Product Usage Process  FDA Received Date 19-Oct-2016  Preferred Term  Cardiac Arrest; Drug D Omission; Product Lab Issue; Product Selection	Case # 12860481  Proc Oose Adre	EXPEDITED (15-DAY)  duct  enalin	Comp.	OTC	Role S	CA-PAR PHARMACEL COMPANIES- 2016SCPR01  Route  Unknown	JTICAL - 5998 <b>Dosage</b> Unk U Unk U	e Text nk, Unknown	-	Unknown Mt	CAN
Technique In Product Usage Process  FDA Received Date  19-Oct-2016  Preferred Term  Cardiac Arrest; Drug D Omission; Product Lab Issue; Product Selection	Case #  12860481  Proceute Adressed Epipen	EXPEDITED (15-DAY)  duct  enalin  en Trainer	Comp.	OTC	Role S S	CA-PAR PHARMACEL COMPANIES- 2016SCPR01  Route  Unknown Unknown	JTICAL - 5998 <b>Dosage</b> Unk U Unk U	e Text nk, Unknown nk, Unknown	<u>Duration</u>	Unknown <u>M</u> t	CAN  fr  ar



Drug Interaction	Xyrer	m			S	Oral		2.25 G, Bid		Ja	ZZ
	Xyrer	m			S	Oral		Dose Adjustment	S	Ja	ZZ
	Xyrer	m			S	Oral		4.5 G, Bid		Ja	ZZ
	Hydro	opril And ochlorothiazide			S			Unknown Dose			
	Hydro	opril And ochlorothiazide			S			Unknown Dose			
	Epipe				S			Unknown Dose			
	Hyar Cyml	ochlorothiazide nalta			C C						
	Levo	thyroxine			С						
		ormin Hcl			С						
	Neur Ritali				C C						
	Adva				С						
	Albut				С						
	Amlo Glybi	dipine Besylate			C C						
		axin-750			Č						
	Cann				С						
		opion Hcl			C C						
		odone Hcl astatin			C						
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	M	Ifr Control #	503B Fac	cility Age	<u>Sex</u>	Country
21-Oct-2016	12868881	NON-EXPEDITED		ŀ	HO, LT		S-PFIZER INC 016488898	;-	15 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	<u>Route</u>		Dosage Text	<u>Duration</u>	Mfr	
Orug Ineffective	Epipe	en			S			Unk		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u> Dutcomes</u>	<u>M</u>	Ifr Control #	503B Fac	cility Age	<u>Sex</u>	Country
21-Oct-2016	12873543	EXPEDITED (15-DAY)		(	OT		S-MYLANLAB 016M1044164			Unknown	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route		Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Asthenia; Dyspepsia;	Epipe	en Auto-Injector			S	Intramus	scular	0.3 Mg, Prn		Му	⁄lan



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Nausea	Pepcid /	00305201/			S			Unk				Mylar	1
	Benadry	rl /00000402/			S			Unk				Mylar	1
	Solume	drol			S			Unk				Mylar	1
	Singulai	r			С	Oral		10 Mg, Qa	m			Mylar	1
	Clarinex	/01202601/			С	Oral		5 Mg, Qpn	า			Mylar	1
	Advair				С	Respirat		500 Mg, B	id			Mylar	1
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	M	Ifr Control #	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>		Country
26-Oct-2016	12858536	EXPEDITED (15-DAY)		1	ОТ		A-PFIZER INC- 016484159				Female	)	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u></u>	osage Te	<u>xt</u>	<b>Duration</b>		<u>Mfr</u>	
Expired Product Administered; Throat Tightness	Epipen				S			Unk				Unkno	own
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	M	Ifr Control #	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	-	Country
27-Oct-2016	12820475	EXPEDITED (15-DAY)			ОТ	_	S-PFIZER INC- 016464176				Unknov	vn	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u> </u>	Oosage Te	<u>xt</u>	<b>Duration</b>		<u>Mfr</u>	
Injection Site Injury; Product Quality Issue	Epipen 、	Jr			S			Unk, Once	•			Pfizer	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	<u>M</u>	Ifr Control #	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	!	Country
28-Oct-2016	12861532	NON-EXPEDITED		1	ОТ		A-PFIZER INC- 016482091				Male		USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u></u>	osage Te	<u>xt</u>	<u>Duration</u>		<u>Mfr</u>	
Drug Ineffective; Expire Product Administered	ed Epipen Epipen				S S			Unk				Unkno	
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	<u>M</u>	Ifr Control #	<u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>		Country
28-Oct-2016	12892425	NON-EXPEDITED					S-PFIZER INC- 016501289			29 YR	Male		USA



							•			
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Injection Site Hypoaesthesia; Injectio Site Pain; Pain In Extremity		Jr			S	Intramuscular	0.3 Mg, Unk		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>503B</u>	Facility Age	<u>Sex</u>	<b>Country</b>
28-Oct-2016	12893099	EXPEDITED (15-DAY)		D	E, LT	US-PFIZER 2016498920		7 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Ineffective	Epipen .	Jr			S		Unk		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B	Facility Age	<u>Sex</u>	Country
28-Oct-2016	12893178	EXPEDITED (15-DAY)		0	Т	CH-MYLAN 2016M1046			Unknown	CHE
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mfr	:
Device Failure; Wrong Technique In Product Usage Process	Epipen				S				Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B	Facility Age	<u>Sex</u>	<u>Country</u>
28-Oct-2016	12893432	NON-EXPEDITED		0	Т	US-PFIZER 2016501275		10 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	:
Accidental Exposure To Product By Child; Palpitations; Tremor	o Epipen				S		Unk		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol # 503B	Facility Age	<u>Sex</u>	Country
04-Nov-2016	12352193	EXPEDITED (15-DAY)		0	Т	ES-MYLANI 2016M1019			Unknown	ESP



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Accidental Exposure T Product; Injection Site Pain; Nervousness	o Epipen				S					Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Nov-2016	12912805	NON-EXPEDITED				US-PFIZI 2016514			70 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Gait Disturbance; Injec Bite Pain; Musculoskel Stiffness; Wrong Fechnique In Product Jsage Process					S S	Intramuscular	0.3 M	g, Prn		Pfiz Pfiz	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Nov-2016	12913354	EXPEDITED (15-DAY)		(	TC	FI-MYLAI 2016M10	_			Unknown	FIN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Malfunction	Epipen .	Junior			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Nov-2016	12921124	EXPEDITED (15-DAY)		(	TC	ES-PFIZE 2016255			42 YR	Female	ESP
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Pain; Nervousness	o Epipen				S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Nov-2016	12838648	EXPEDITED (15-DAY)		(	TC	US-MYLA 2016M10				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose Epipen A	Auto-Injector			S		0.3 M	g, Once		Му	lan



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Nov-2016	12945722	EXPEDITED (15-DAY)		С	T	US-MYLA 2016M10				Unknowr	n USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>∕/fr</u>
Device Failure; Drug D Omission	ose Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		l	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Nov-2016	12945728	EXPEDITED (15-DAY)		Н	10	US-MYLA 2016M10	_			Unknowr	n USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Device Failure	Epipen	Auto-Injector			S		Unk, F	rn		l	Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	<u>outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Nov-2016	12592642	NON-EXPEDITED				PHEH201	6US018077		17 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Product Use In		Injection			S	Unknown	Unk			I	Novartis
Unapproved Indication Rash; Urticaria	i; Epipen				S	Unknown	Unk				
,	Advair				С	Unknown	Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Nov-2016	12908438	NON-EXPEDITED				US-PFIZE 20153583	-		78 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Drug Hypersensitivity; Iodine Allergy	Epipen				S		0.3 G, 0.3g)	Unk (Auto Injector		I	Pfizer
	Iodine				S	Oral	Unk				



							-				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Nov-2016	12957569	EXPEDITED (15-DAY)		l	_T	ZA-MYLANL 2016M1050				Unknown	ZAF
Preferred Term	Produc	<u>et</u>	Comp.	<u>otc</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Jr			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Nov-2016	12965510	EXPEDITED (15-DAY)		(	TC	US-MYLANI 2016M1049				Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose Epipen	Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Nov-2016	12937184	NON-EXPEDITED				US-PFIZER 2016525485			16 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Anxiety; Feeli Jittery; Heart Rate Increased; Injection Sit Haemorrhage; Palpitat	ing				S	Intramuscular	0.3 M	g, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Nov-2016	12969083	DIRECT	Υ	(	TC				6 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Aggression; Device Malfunction; Injection S Erosion; Injection Site Laceration; Patient Uncooperative	Epi Per Site	n Jr			S					Me	ridian



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Nov-2016	12835857	EXPEDITED (15-DAY)			HO, OT	JP-PFIZER IN0 2016464855	) <del>.</del>	79 YR	Female	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock;	Epipen (	0.3mg			S	Subcutaneous	0.3 Mg, Single		Pfiz	zer
Asthenia; Tremor	Lyrica				С		125 Mg, Daily 50 Mg In The Morning And 75 Mg Ir The Evening	1		
	Opalmo	n			С	Oral	5 Ug, 3x/Day			
	Mecoba	lamin			С	Oral	1 Df, 3x/Day			
	Mucosta	l			С		100 Mg, 3x/Day			
	Alinamir	ı F			С	Oral	50 Mg, 2x/Day			
	Edirol				С		0.75 Ug, 1x/Day			
	Myslee			С		5 Mg, 1x/Day Before Bedtime				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Nov-2016	12982218	NON-EXPEDITED				US-PFIZER IN 2016544898	C-		Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Tremor	Epipen				S		Unk, Prn		Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Dec-2016	12911496	EXPEDITED (15-DAY)			ОТ	BE-MYLANLAI 2016M104766			Unknown	BEL
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen /	Auto-Injector			S	Subcutaneous	0.3 Mg, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Dec-2016	12937133	EXPEDITED (15-DAY)			ОТ	US-MYLANLAI 2016M104892			Unknown	USA



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	red Term Product					Dotalloa I	орон			
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Laceration		r. Auto-Injector r. Auto-Injector			S S	Intramuscular	0.15 Mg, Once		Myl Myl	
FDA Received Date Ca	ıse #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Dec-2016 12	990575	EXPEDITED (15-DAY)		01	Γ	AT-MYLANL 2016M10526	=		Unknown	AUT
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Malfunction	Epipen				S		Unk		Myl	an
FDA Received Date Ca	ise#	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Dec-2016 12	982197	NON-EXPEDITED				US-PFIZER 2016544899	NC-	8 YR	Male	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product By Child; Injection Site Bruising	Epipen 1				S		Unk		Pfiz	er
FDA Received Date Ca	ıse #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Dec-2016 12	947439	EXPEDITED (15-DAY)		01	Г	US-PFIZER 2016530429	NC-	6 YR	Female	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Laceration; Needle Issue	Epipen J	r			S	Intramuscular	0.15 Mg, Once		Pfiz	zer
FDA Received Date Ca	ise #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Dec-2016 12	980484	EXPEDITED (15-DAY)		НС	O, OT	JP-MYLANL 2016M10438			Unknown	JPN
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Anaphylactic Shock;	Epipen				S	Subcutaneous	0.3 Mg, Total		Myl	an



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								The Morning And 75 Mg I The Evening	n		
	Opalm	on			С	Oral		5 Mg, Tid		Му	lan
	Mecob	palamin			С	Oral		1 Df, Tid		Му	lan
	Mucos	ta			С			100 Mg, Tid		Му	lan
	Alinam	nin F /00257801/			С	Oral		50 Mg, Bid		Му	lan
	Edirol				С			0.75 Mg, Qd		Му	lan
	Myslee	9			С			5 Mg, Qd Before Bedtime		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2016	13009041	EXPEDITED (15-DAY)		C	T		JP-PFIZER INC- 2016560919			Unknown	JPN
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Rout	<u>e</u>	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Autism Spectrum Diso	rder Epiper	n			S			Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Dec-2016	12953137	EXPEDITED (15-DAY)		C	T		FI-MYLANLABS 2016M1046458			Unknown	FIN
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Rout	<u>e</u> .	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Malfunction	e Epiper	n Jr			S			Daily Dose: 0.15 Mg Millgram(S) Every Total		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Dec-2016	13014498	EXPEDITED (15-DAY)		C	T		JP-MYLANLABS 2016M1054578	<del>)-</del>		Unknown	JPN
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Rout	<u>e</u>	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Autism Spectrum Diso	rder Epiper	١			S			Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>		Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Dec-2016	13017235	EXPEDITED (15-DAY)		С	E, OT		US-PFIZER INC 2016570497	-		Female	USA



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Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Completed Suicide	Epipen				S		Unk			i	Pfizer
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Dec-2016	13009050	EXPEDITED (15-DAY)			ОТ	US-PFIZEF 201656447				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product; Injection Site Injury; Skeletal Injury					S		Unk			I	Pfizer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Dec-2016	13026636	EXPEDITED (15-DAY)			ОТ	SE-PFIZEF 201657566			5 YR	Male	SWE
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product By Child; Inject Site Injury					S	Intramuscular	Unk			I	Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Dec-2016	13035112	EXPEDITED (15-DAY)			ОТ	US-PFIZEF 201658233	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	Text	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Loss Of Consciousnes	ss Epipen				S		Unk			ſ	Pfizer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Dec-2016	13036503	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2016M105				Unknowr	n USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	Text	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Drug Effect Incomplete		Auto-Injector			S	Intramuscular	0.3 Mg	, Once		ı	Mylan
Hypoaesthesia; Injection Site Pain; Injection Site Swelling		Auto-Injector			S	Intramuscular	0.3 Mg	, Once			Mylan

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.



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	Epipen Auto-Injector				S	Intrar	muscular	0.3 Mg	, Once			Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Dec-2016	13042683	NON-EXPEDITED			LT, OT		US-PFIZER IN 2016586505	C-		19 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTO	Role	Rou	<u>te</u>	Dosage	<u>Text</u>	<u>Duration</u>	<u>!</u>	<u> Mfr</u>
Drug Effect Incomplete Hypoaesthesia; Injectic Site Pain; Injection Site Swelling	on	Jr			S	Intrar	muscular	0.3 Mg				Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes		Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Dec-2016	13051606	EXPEDITED (15-DAY)			ОТ		US-PFIZER IN 2016586504	C-		5 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTO	Role	Rou	<u>te</u>	<u>Dosage</u>	Text	<b>Duration</b>	<u>!</u>	<u>Mfr</u>
Injection Site Laceration	n Epipen	Jr			S	Intrar	muscular	0.15 M	g, Prn			Pfizer
	Diphen	hydramine Hcl			S			Unk				Unknown
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes		Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Dec-2016	13008569	NON-EXPEDITED			DE, HO, LT	, OT	US-PFIZER IN 2016560625	C-		11 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	<u>Rou</u>	<u>te</u>	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>!</u>	<u>VIfr</u>
Drug Ineffective	Epipen				S			Unk Ur	nk, Once			Pfizer
	Epipen				S			Unk, O	nce			Pfizer
	Epipen				S			Unk, O	nce			Pfizer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Dec-2016	13055501	EXPEDITED (15-DAY)			ОТ		US-MYLANLAE 2016M1055614				Unknow	n USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTO	Role	Rou	<u>te</u>	<u>Dosage</u>	Text	<b>Duration</b>	<u>!</u>	<u>VIfr</u>
Drug Effect Incomplete	e Epipen	Jr. Auto-Injector			S			Hok Hr	nk, Once			Mylan



	Epipen	Jr. Auto-Injector	S			Unl	k, Once		My	/lan	
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Dec-2016	13063640	NON-EXPEDITED		(	TC	US-PFIZE 20165961				Male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>otc</u>	Role	Route	Dosa	age Text	<b>Duration</b>	<u>Mf</u> ı	:
Drug Effect Incomplete	e Epipen	Jr			S		Unl	k Unk, Once		Pf	zer
	Epipen	Jr			S		Unl	k, Once		Pf	zer
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Dec-2016	13066737	NON-EXPEDITED		ŀ	HO, LT, OT	US-PFIZE 20165961				Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>otc</u>	Role	Route	Dosa	age Text	<u>Duration</u>	<u>Mf</u> ı	
Drug Ineffective	Epipen				S		Unl	k, Once		Pf	zer
	Epipen				S			k, Once		Pf	zer
	Epipen				S		Unl	k, Once		Pf	zer
	Epipen				S		Unl	k, Once		Pf	zer
	Epipen				S		Unl	k, Once		Pf	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Dec-2016	13074137	EXPEDITED (15-DAY)		(	TC	FI-MYLAI 2016M10				Unknown	FIN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<b>Duration</b>	<u>Mf</u> ı	
Injection Site Injury; Injection Site Scar; Ne Issue	Epipen edle	Jr			S		Unl	ζ		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Dec-2016	13076890	EXPEDITED (15-DAY)		(	ЭТ	FI-PFIZE 20166021			4 YR	Unknown	FIN
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<b>Duration</b>	<u>Mfı</u>	•



njection Site Injury; njection Site Scar; Nee ssue	Epipen J edle	r			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jan-2017	13045982	EXPEDITED (15-DAY)			НО	US-PFIZER 2016582831	INC-		20 YR	Male	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foreign Body; Injection Site Injury; Product Administered At nappropriate Site	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jan-2017	13081052	NON-EXPEDITED				US-PFIZER 2016603948				Female	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Injection Site njury; Product Quality ssue	o Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Jan-2017	13085423	NON-EXPEDITED				US-PFIZER 2016603958			304 DAY	Female	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
njection Site Bruising; njection Site Injury; Product Quality Issue	Epipen Benadry	l.			S C	Intramuscular Oral	0.15 I Unk,	Mg, Prn Prn		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	l#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jan-2017	13092883	DIRECT	Υ		ОТ				8 YR	Male	USA
Preferred Term	Product		Comp.	OTC	<u>Role</u>	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	Mfr	



Anaphylactic Reaction; Injection Site Bruising; Injection Site Pain; Needle Epi-Pen Jr, 0.15 Mg Mylan

Intramuscular

S

Mylan

Injection Site Pain; Ne Issue	edle										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jan-2017	13106975	EXPEDITED (15-DAY)		0	Т	NO-MYL 2017M1	_ANLABS- 001642			Unknown	NOR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Malfunction	e Epipen /	Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jan-2017	13114101	NON-EXPEDITED		Н	O, LT	US-PFIZ 2017007	ZER INC- 7174			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Dose Omission					S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jan-2017	13122337	EXPEDITED (15-DAY)		0	Т	SE-MYL 2017M1	ANLABS- 002762			Unknown	SWE
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Fatigue					S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jan-2017	13122896	EXPEDITED (15-DAY)		0	Т	US-PFIZ 2017007	ZER INC- 7098			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Needle Issue	e Epipen				S		Unk			Pfiz	er



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>ıtcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2017	13130697	EXPEDITED (15-DAY)		07	Г	US-PFIZER 2017016200	-		59 YR	Male	JAM
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Expired Product Administered	d Epipe	n 0.3mg			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2017	13131395	EXPEDITED (15-DAY)		Н	)	NZ-MYLAN 2017M1003				Unknown	NZL
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Expired Product Administered	oduct Administered				S		300 M	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2017	13131669	EXPEDITED (15-DAY)		LT	, OT	US-MYLAN 2017M1001	_			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof Ou	ıtcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jan-2017	13055467	EXPEDITED (15-DAY)		Н	)	US-MYLAN 2016M1056				Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Stress Cardiomyopath	y; Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	lan
Syncope	Losar	tan			С		Unk			Му	lan
	Synth	roid			С		Unk			Му	lan
	Probi	otic /06395501/			С		Unk			Му	lan
	Vitam	in D /00107901/			С		Unk			Му	lan
	Montelukast				С		Unk			My	lan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jan-2017	13122753	EXPEDITED (15-DAY)			LT	FR-MYLANI 2017M1002				Unknown	FRA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; Needle Issue	e Epipen				S	Subcutaneous	Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jan-2017	13139997	NON-EXPEDITED			LT, OT	US-PFIZER 2017026499			53 YR	Female	USA
Preferred Term	Product	<u>I</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure	Epipen				S	Intramuscular	0.3 Mg	g, As Needed(Prn)		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jan-2017	13140659	EXPEDITED (15-DAY)			НО	JP-MYLANL 2017M1003				Unknown	JPN
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure	Epipen ( Injector	Epinephrine) Auto 0.3 Mg			S	Intramuscular	0.3 Mg	g, Single		Myl	an
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jan-2017	13141129	EXPEDITED (15-DAY)			LT, OT	US-PFIZER 2017026500			55 YR	Female	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Drug Ineffective; Inject Site Pain; Injection Site Warmth; Injury Associa With Device; Vomiting	e ated				S	Intramuscular	0.3 M	g, Once		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jan-2017	13144066	NON-EXPEDITED				US-PFIZER	INC-		8 YR	Male	USA



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Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mfr	
Device Issue; Injection Site Pain; Injury Associated With Device					S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
24-Jan-2017	13145366	EXPEDITED (15-DAY)		I	_T, OT	US-MYLANI 2017M1003				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage '	<u>Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Injecti Site Pain; Injection Site Warmth; Injury Associa With Device; Vomiting	Э	Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jan-2017	13145592	EXPEDITED (15-DAY)		I	Ю	NZ-PFIZER 2017031486	-		13 YR	Male	NZL
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	Mfr	
Device Failure; Expired Product Administered	d Epipen				S		300 Mg	, Prn		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jan-2017	13145673	EXPEDITED (15-DAY)		(	OT	BE-PFIZER 2016515921	-		57 YR	Female	BEL
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage '	<u>Text</u>	<b>Duration</b>	Mfr	
Device Failure; Device Issue; Incorrect Route Drug Administration	evice Failure; Device Epipen sue; Incorrect Route Of				S	Subcutaneous	0.3 Mg,	Unk		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
		EXPEDITED (15-DAY)		I	НО	US-PFIZER			75 YR	Female	USA
25-Jan-2017	13068670	EXILUITED (13-DX1)				2016596131					



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Stress Cardiomyopathy	/; Epipen				S	Intramuscular	0.3 Mg	g, Prn		Pfiz	zer
Syncope	Losartai	า			С		Unk				
	Synthro	id			С		Unk				
	Probioti	C			С		Unk				
	Vitamin	D			С		Unk				
	Montelu	kast			С		Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jan-2017	13154099	EXPEDITED (15-DAY)		0.	Т	US-MYLANI 2017M10030	-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipen A	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Myl	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jan-2017	13089358	EXPEDITED (15-DAY)		0	Т	US-PFIZER 2016605435				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Device Failure; Device Use Issue; Expired Product Administered	Epipen				S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jan-2017	13131308	EXPEDITED (15-DAY)		0.	Т	CA-PFIZER 2017007195				Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Drug Dose Omission; Needle Issue	Epipen				S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jan-2017	13159596	EXPEDITED (15-DAY)		0.	Т	US-PFIZER 2017038434			55 YR	Female	USA
Preferred Term	I Term Product		Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	Mfr	



Device Failure; Needle Issue	e Epipen				S	Intramuscular	0.3 Mg	, Once	Pfizer		zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jan-2017	13076807	EXPEDITED (15-DAY)		0	Т	JP-MYLANL 2016M1059				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Expire Product Administered	ed Epipen				S	Intramuscular	Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jan-2017	13076810	EXPEDITED (15-DAY)		0.	Т	JP-MYLANL 2016M1059				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
rug Effect Incomplete; Epipen xpired Product dministered				S		Unk			Му	lan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2017	13164710	EXPEDITED (15-DAY)		L1	Г	AU-MYLANI 2017M1004				Unknown	AUS
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen Injector	(Epinephrine) Auto 0.3 Mg			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2017	13167762	NON-EXPEDITED				US-PFIZER 2017038433			64 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Anxiety; Expir Product Administered; Feeling Jittery	red				S	Intramuscular	0.3 Mg	ı, Once		Pfi	zer



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>1# 503B Fac</u>	ility Age	<u>Sex</u>	Country
06-Feb-2017	13066730	NON-EXPEDITED		Lī	г, ОТ	US-PFIZER 2016596128			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<u>Duration</u>	Mfr	:
Drug Ineffective; Intentional Product Misuse; Liquid Produc Physical Issue	Epipen ct				S		Unk		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>1#</u> <u>503B Fac</u>	ility Age	<u>Sex</u>	Country
06-Feb-2017	13143405	EXPEDITED (15-DAY)			Т	US-PFIZER 2017028162		27 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	• •
ccidental Exposure To Epipen Jr roduct; Device Defective; Sertraline xpired Product Venlafaxine dministered; Injury ssociated With Device; keletal Injury				S C C		100 Mg, Unk 75 Mg, Unk		Pfi	zer	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>1#</u> <u>503B Fac</u>	<u>ility Age</u>	<u>Sex</u>	Country
07-Feb-2017					_		LDI 2047	52 YR		0.4.1.
07 1 00 2017	13191611	EXPEDITED (15-DAY)		Н	O	CA-BAUSCH 002648	1-BL-2017-	52 fR	Male	CAN
	13191611 <u>Produ</u>	, ,	Comp.	OTC	Role		Dosage Text	Duration	Male <u>Mfr</u>	
Preferred Term	Produ Besiva Ophtha	ct nce (Besifloxacin Ilmic Suspension) 0.6%	Comp.		Role S	002648			<u>Mfr</u>	
Preferred Term	Produ Besiva Ophtha Amlodi	ct nce (Besifloxacin Ilmic Suspension) 0.6% pine	Comp.		Role S S	002648  Route  Unknown  Oral			<u>Mfr</u>	:
Preferred Term	Produ Besiva Ophtha Amlodi Betopti	ct nce (Besifloxacin Ilmic Suspension) 0.6%	Comp.		Role S S S	002648  Route  Unknown			<u>Mfr</u>	:
Preferred Term	Produ Besiva Ophtha Amlodi Betopti Cialis	nce (Besifloxacin Ilmic Suspension) 0.6% pine c S Oph Sus 0.25%	Comp.		Role S S S S	002648  Route  Unknown  Oral	Dosage Text		<u>Mfr</u>	:
Preferred Term	Produ  Besiva Ophtha Amlodi Betopti Cialis Epipen	nce (Besifloxacin Ilmic Suspension) 0.6% pine c S Oph Sus 0.25%	Comp.		Role S S S S S S	002648  Route  Unknown  Oral  Unknown			<u>Mfr</u>	:
Preferred Term  Hypersensitivity	Produ Besiva Ophtha Amlodi Betopti Cialis	nce (Besifloxacin Ilmic Suspension) 0.6% pine c S Oph Sus 0.25%	Comp.		Role S S S S	002648  Route  Unknown  Oral  Unknown  Unknown	Dosage Text		<u>Mfr</u>	:



						Dotanioa	Noport				
	Ratio-P	rednisolone			S	Unknown					
	Ratio-P	rednisolone			S	Unknown					
	Teva-Pr	rednisone			S	Unknown					
	Vigamo	x			S	Unknown					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Feb-2017	13192221	DIRECT	Υ							Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Needle Issue; Wrong Technique In Product Usage Process	Epipen				S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2017	13205637	EXPEDITED (15-DAY)		(	TC	IE-PFIZEI 20170597				Female	IRL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Discolouration; Injectio Site Hypoaesthesia		0.3mg			S		Unk			Pfiz	eer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	12083605	NON-EXPEDITED				US-MYLA 2015M10-			69 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Injury Associated With Devic		Auto-Injector			S	Unknown	Unk			Myl	an
	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date											
16-Feb-2017	12083607	NON-EXPEDITED				US-MYLA 2015M10	-		9 YR	Male	USA



Accidental Exposure 1 Product By Child; Hea Rate Increased	uct By Child; Heart				S	0.3 Unk, Unk		nk, Unk	Mylan		Mylan
	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13007216	EXPEDITED (15-DAY)			ОТ	JP-MYLAN 2016M105	-			Unknown	JPN
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Accidental Exposure T Product; Expired Prod Administered; Injection Site Haemorrhage	uct	en			S		Unk			N	∕lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
16-Feb-2017	13241279	NON-EXPEDITED				US-MYLAN 2016M100				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Device Failure	Epipe	en Auto-Injector			S		0.3 M	g, Prn		Ņ	Mylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241284	NON-EXPEDITED				US-MYLAN 2015M104	_		18 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 M	g, Prn		N	Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241287	NON-EXPEDITED				US-MYLAN 2016M100				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Accidental Exposure 1 Product	ccidental Exposure To Epipen Auto-Injector				S		Unk			N	Mylan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241290	NON-EXPEDITED				US-MYLAN 2016M1003			45 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Expired Produ Administered		n Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Once		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241292	EXPEDITED (15-DAY)		(	ОТ	US-MYLAN 2016M1002			81 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injury Associated With Device	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241295	NON-EXPEDITED				US-MYLAN 2016M1001				Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Accidental Exposure To Product	o Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241297	NON-EXPEDITED				US-MYLAN 2016M1001				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mfr	
Contusion	Epipe	n Trainer			S		Unk			Му	⁄lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241305	NON-EXPEDITED				US-MYLAN 2016M1002			21 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	



Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		M	ylan	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
16-Feb-2017	13241306	NON-EXPEDITED				US-MYLAN 2016M1004	-		72 YR	Female	USA	
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mf	<u>r</u>	
Accidental Exposure T Product; Injection Site Pallor		n Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		M	ylan	
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
16-Feb-2017	13241309	NON-EXPEDITED				US-MYLAN 2016M1008	-		57 YR	57 YR Female		
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u> <u>Mfr</u>		<u>r</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		ylan		
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
16-Feb-2017	13241311	NON-EXPEDITED				US-MYLAN 2016M1000	-		44 YR	Female	USA	
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mf	<u>r</u>	
Accidental Exposure T Product; Unevaluable Event	ō Epipe	n Auto-Injector			S	Unknown	Unk			M	ylan	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
16-Feb-2017	13241312	NON-EXPEDITED				US-MYLAN 2016M1002				Male	USA	
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mf	<u>r</u>	
Accidental Exposure T Product; Expired Prod Administered		en Auto-Injector			S		Unk			M	ylan	



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FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241316	NON-EXPEDITED				US-MYLAN 2016M1006	-		4 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Injection Site Bruising; Injection Site Pain; Inju Associated With Devic	ıry	n Jr. Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241320	NON-EXPEDITED				US-MYLAN 2016M1007			60 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S Intramuscular 0.3 Mg, Prn					Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241325	NON-EXPEDITED				US-MYLAN 2016M1010	-		2 YR	Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15 N	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241330	NON-EXPEDITED				US-MYLAN 2016M1008			20 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241331	NON-EXPEDITED				US-MYLAN 2016M1012	-		26 YR	Female	USA
Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage	Toyt	<u>Duration</u> <u>Mfr</u>		



Accidental Exposure To Product; Device Failure; njection Site Bruising		Auto-Injector Auto-Injector			S S	Intramuscular	0.3 Mg, C	Once		My My	
FDA Received Date Ca	ase #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	<u>#</u> 5	03B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017 13	241336	NON-EXPEDITED				US-MYLANLA 2016M101306			39 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>otc</u>	Role	Route	Dosage T	<u>ext</u>	<b>Duration</b>	Mfr	
Feeling Jittery; Heart Rate ncreased; Injection Site Bruising; Injection Site Haemorrhage; Product Administered At nappropriate Site	e Epipen <i>i</i>	Auto-Injector			S		0.3 Mg, L	Jnk		Му	lan
FDA Received Date Ca	ase #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017 13	241340	NON-EXPEDITED				US-MYLANLA 2016M100889			48 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<b>Duration</b>	Mfr	
Device Failure; Injection Site Haemorrhage	Epipen /	Auto-Injector			S	Intramuscular	0.3 Mg, F	Prn		Му	lan
FDA Received Date Ca	ase #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2017 13	241341	NON-EXPEDITED				US-MYLANLA 2016M101192			70 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage T	<u>ext</u>	<b>Duration</b>	Mfr	
Accidental Exposure To Product; Expired Product Administered	Epipen <i>i</i>	Auto-Injector			S		Unk			Му	an
FDA Received Date Ca	ase #	Case Type	Health	Prof	Outcomes	Mfr Control	# 5	03B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2017 13	241370	NON-EXPEDITED				US-MYLANLA 2016M101391			49 YR	Female	USA
Preferred Term	Produc	+	Comp.	OTC	Role	Route	Dosage T	ovt	<u>Duration</u>	Mfr	



Device Failure; Expire Product Administered; Feeling Jittery	oduct Administered; eling Jittery				S	Intramuscular	0.3 Mg, Onc	e		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol # 5031	B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241376	NON-EXPEDITED				US-MYLAN 2016M1016	-			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text		<b>Duration</b>	Mf	r
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn			М	ylan
		n Auto-Injector n Auto-Injector			S S						ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol # 503l	B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241385	NON-EXPEDITED				US-MYLAN 2016M1020	-		15 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text		<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Injection Site Bruising		en Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol # <u>503</u> 1	B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241388	NON-EXPEDITED				US-MYLAN 2016M1013			69 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text		<b>Duration</b>	Mf	<u>r</u>
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol # <u>503</u> 1	B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241390	NON-EXPEDITED				US-MYLAN 2016M1016			10 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	<b>Dosage Text</b>		<b>Duration</b>	<u>Mf</u>	<u>r</u>
Device Failure		en Jr. Auto-Injector			S	Intramuscular	0.15 Mg, Pri	า			ylan
		n Jr. Auto-Injector			S	Intramuscular	0.13 Mg, 1 H	1			ylan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241391	NON-EXPEDITED				US-MYLAN 2016M1018	_		6 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Epistaxis	o Epipe	n Jr. Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241403	NON-EXPEDITED				US-MYLAN 2016M1019	_		65 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn If Needed		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241413	NON-EXPEDITED				US-MYLAN 2016M1018				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Drug Effect Decreased Expired Product Administered	l; Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241451	NON-EXPEDITED				US-MYLAN 2016M1021				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injury Associated With Device	Epipe	n Jr. Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241455	NON-EXPEDITED				US-MYLAN 2016M1023			45 YR	Female	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosage	Tavt	Duration	Mfr	



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Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 N	lg, Once		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241468	NON-EXPEDITED				US-MYLAN 2016M1026				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product	o Epipe	n Jr. Auto-Injector			S		0.15	Mg, Once		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241469	NON-EXPEDITED				US-MYLAN 2016M1024	-			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Auto-Injector			S		0.3 N	lg, Unk		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241471	NON-EXPEDITED				US-MYLAN 2016M1025			5 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	:
Injection Site Bruising	Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Prn		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241473	NON-EXPEDITED				US-MYLAN 2016M1024				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Injury Associa With Device		n Auto-Injector			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241480	NON-EXPEDITED				US-MYLAN 2016M1027			27 YR	Male	USA



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Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	, Prn		ľ	Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241491	NON-EXPEDITED				US-MYLANI 2016M1029			44 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product; Expired Prod Administered; No Adve Event	uct	n Auto-Injector			S		Unk			N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241493	NON-EXPEDITED				US-MYLANI 2016M1032	_		63 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product; Expired Prod Administered; Injectior Site Pain; Wrong Technique In Product Usage Process	uct	n Auto-Injector			S		Unk, O	nce		N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241494	NON-EXPEDITED				US-MYLANI 2016M1028				Female	USA
Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	, Prn		<u> </u>	Mylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241495	NON-EXPEDITED				US-MYLANI 2016M1030			3 YR	Male	USA
				OTC	Role	Route	Dosage		Duration	M	



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Drug Prescribing Error Adverse Event	r; No Ep	pen Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>1#</u> 503B Fa	acility Age	<u>Sex</u>	Country
16-Feb-2017	13241499	NON-EXPEDITED				US-MYLANL 2016M10240		65 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Prod Administered; Injection Site Bruising; Injection Coldness; Injection Sit Hypoaesthesia; Injection Site Site Injury; Injection Site Pain; Injection Site Swelling; Pain In Extremity; Palpitations	luct n n Site te ion ite	pen Auto-Injector			S		Unk		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	<u>1#</u> 503B Fa	cility Age	<u>Sex</u>	Country
16-Feb-2017	13241500	NON-EXPEDITED				US-MYLANL 2016M10278			Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>otc</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Device Failure	Ep	pen Auto-Injector			S		0.3 Unk, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	<u>l#</u> <u>503B Fa</u>	acility Age	<u>Sex</u>	Country
16-Feb-2017	13241552	NON-EXPEDITED				US-MYLANL 2016M10535	-	49 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	OTC	Role	<u>Route</u>	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product	Го Ер	pen Auto-Injector			S	Intramuscular	0.3 Mg, Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	<u>1#</u> 503B Fa	cility Age	<u>Sex</u>	Country
16-Feb-2017	13241554	NON-EXPEDITED		US-MYLANLABS- 2016M1035905				Female	USA	
Preferred Term	Dr	<u>oduct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	<u>Mfr</u>	



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Drug Screen False Positive	Epipe	n Auto-Injector			S		Unk,	Prn		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241556	NON-EXPEDITED				US-MYLAN 2016M1034				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	Mf	<u>.</u>
Accidental Exposure T Product; Expired Prod Administered; Injection Site Laceration	uct	n Auto-Injector			S		Unk,	Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241558	NON-EXPEDITED				US-MYLAN 2016M1012			48 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mf	<u>.</u>
Accidental Exposure T Product; Feeling Jitter Palpitations		n Auto-Injector			S	Intramuscular	Unk,	Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
16-Feb-2017	13241561	NON-EXPEDITED				US-MYLAN 2016M1039	-		3 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	Mf	<u>.</u>
Accidental Exposure T Product By Child	Го Еріре	n Jr. Auto-Injector			S	Intramuscular	0.15 I	Mg, Prn		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241564	NON-EXPEDITED				US-MYLAN 2016M1043				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	Mf	<u>.</u>
Accidental Exposure T Product; Expired Prod Administered; No Adve Event	uct	en Jr. Auto-Injector			S		Unk			M	ylan

Date - Time: 15-May-2018 01:32:07 PM EST



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FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241565	NON-EXPEDITED				US-MYLAI 2016M103				Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Incorrect Dose Administered	Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15 l	Mg, Prn		My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241568	NON-EXPEDITED				US-MYLAI 2016M101			69 YR	Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Auto-Injector			S	Unknown	Unk,	Prn		My	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241578	NON-EXPEDITED				US-MYLAI 2016M104			2 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product By Child	o Epipe	n Auto-Injector			S		Unk			My	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241583	NON-EXPEDITED				US-MYLAI 2016M105			55 YR	Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug D Omission	Dose Epipe	n Auto-Injector			S	Intramuscular	0.3 M	lg, Once		My	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241585	NON-EXPEDITED				US-MYLAI 2016M103	_			Female	USA
Preferred Term		uct	Comp.	отс	Role	Route		<u>je Text</u>	<b>Duration</b>	Mfr	



Accidental Exposure T Product	o Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn		My	lan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	I# <u>503B Fa</u>	cility Age	<u>Sex</u>	Country
16-Feb-2017	13241587	NON-EXPEDITED				US-MYLANL 2016M10464		70 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Gait Disturbance; Injec Site Pain; Musculoskel Stiffness; Wrong Technique In Product Usage Process	lotal	n Auto-Injector n Auto-Injector			S S	Intramuscular	0.3 Mg, Prn		Myl Myl	
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	I# <u>503B Fa</u>	cility Age	<u>Sex</u>	Country
16-Feb-2017	13241590	NON-EXPEDITED				US-MYLANL 2016M10499		67 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn		My	lan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	I# <u>503B Fa</u>	cility Age	<u>Sex</u>	Country
16-Feb-2017	13241591	NON-EXPEDITED				US-MYLANL 2016M10364			Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S		Unk, Prn		My	lan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	I# <u>503B Fa</u>	cility Age	<u>Sex</u>	Country
16-Feb-2017	13241592	EXPEDITED (15-DAY)		C	T	US-MYLANL 2016M10547		5 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Injection Site Laceration	on Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15 Mg, Prn		My	an



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FDA Received Date	Coco #	Case Type	Lloolth	Drof O	outcomes	Mfr Contro	ol #	503B Facility	A ===	Cov	Country
			пеанн	<u>Pioi</u> U	utcomes			503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241596	NON-EXPEDITED				US-MYLAN 2016M1044			26 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Device Failure; Drug D Omission	ose Epiper	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		N	⁄lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241598	EXPEDITED (15-DAY)		С	T	US-MYLAN 2016M1044	-		10 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product By Child; Palpitations; Tremor	o Epiper	n Auto-Injector			S		Unk			N	<i>l</i> lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241600	NON-EXPEDITED				US-MYLAN 2016M1031	-		3 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product By Child; Psychomotor Hyperac		n Jr. Auto-Injector			S		Unk, (	Once		N	<i>l</i> lylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241603	NON-EXPEDITED				US-MYLAN 2016M1047			16 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product; Anxiety; Feeli Jittery; Heart Rate Increased; Injection Si Haemorrhage; Palpitat	ing te	n Auto-Injector			S	Intramuscular	0.3 M	g, Once		N	<i>I</i> lylan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2017	13241605	NON-EXPEDITED				US-MYLA 2016M103	_		69 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure	Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Once		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2017	13241607	NON-EXPEDITED				US-MYLA 2016M102	_		5 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Heart Rate Increased; Injury Associated With Devic Oxygen Saturation Decreased		n Auto-Injector			S		0.3 N	Mg, Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241609	NON-EXPEDITED				US-MYLA 2016M103				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	g <u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Expired Product Administered	Epipe	n Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2017	13241614	NON-EXPEDITED				US-MYLA 2016M103			10 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Intercepted Drug Prescribing Error; No Adverse Event	Epipe	n Jr. Auto-Injector			S		0.15	Mg, Unk		M	ylan



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241615	NON-EXPEDITED				US-MYLAN 2016M1048			51 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mf</u> ı	•
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241617	NON-EXPEDITED				US-MYLAN 2016M1039	_		48 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfı</u>	• •
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241624	NON-EXPEDITED				US-MYLAN 2016M1036			82 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	<u>Mfı</u>	
Orug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u> Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241627	NON-EXPEDITED				US-MYLAN 2016M1043			28 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfı</u>	:
Device Failure; Expire Product Administered; Maternal Exposure Du Pregnancy		Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241637	NON-EXPEDITED				US-MYLAN 2016M1045			29 YR	Male	USA
Preferred Term	Produc	<b>~</b> 4	Comp.	ОТС	Role	Route	Dosage	<b>-</b>	Duration	<u>Mfı</u>	



Accidental Exposure To Product; Injection Site Hypoaesthesia; Injection Epipen Auto-Injector

Intramuscular

S

0.3 Mg, Unk

Mylan

Site Pain; Pain In Extremity	OII										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241648	NON-EXPEDITED				US-MYLAN 2016M1041	_		8 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Accidental Exposure T Product By Child	o Epiper	n Jr. Auto-Injector			S		0.15	Mg, Once		N	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241651	NON-EXPEDITED				US-MYLAN 2016M1043				Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Accidental Exposure T Product	o Epiper	n Auto-Injector			S	Intramuscular	Unk			N	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241657	NON-EXPEDITED				US-MYLAN 2016M1043			3 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>M</u> 1	<u>fr</u>
Accidental Exposure T Product By Child; Injective Discolouration; Injection Site Pain		n Jr. Auto-Injector			S		Unk			M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241663	NON-EXPEDITED				US-MYLAN 2016M1038	-		38 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Accidental Exposure T Product; Injection Site	o Epiper	n Auto-Injector			S	Intramuscular	0.3 M	lg, Prn		M	lylan

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Hypoaesthesia; Intentional

P	roc	luct	Misuse	

Product Misuse											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241688	NON-EXPEDITED				US-MYLAN 2016M1043				Unknown	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Off Label Use	Epipe	n Auto-Injector			S		Unk N	/lg, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241693	NON-EXPEDITED				US-MYLAN 2016M1050	_		8 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose Epipe	n Auto-Injector			S		0.3 M	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
16-Feb-2017	13241695	NON-EXPEDITED				US-MYLAN 2016M1043				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Expired Produ Administered; No Adve Event	uct	n Jr. Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241697	NON-EXPEDITED				US-MYLAN 2016M104				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15	Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241702	NON-EXPEDITED				US-MYLAN 2016M1032			77 YR	Female	USA
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							10p0.1			
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, Once		Му	vlan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241705	NON-EXPEDITED				US-MYLAN 2016M1043			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Expired Prod Administered; No Adve Event	uct	n Jr. Auto-Injector			S		Unk		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241708	NON-EXPEDITED				US-MYLAN 2016M1050			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Tremor	Epipe	n Auto-Injector			S		Unk, Prn		Му	vlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13241729	NON-EXPEDITED				US-MYLAN 2016M1039		50 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Anxiety; Tachycardia	Го Еріре	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242056	NON-EXPEDITED				US-MYLAN 2016M1036			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Intentional Product Misuse; No Adverse E		n Auto-Injector			S	Intramuscular	0.3 Mg, Once		Му	rlan



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242059	NON-EXPEDITED				US-MYLAN 2016M103			74 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242060	NON-EXPEDITED				US-MYLAN 2016M104			53 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 M	g, Once		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	rol#	503B Facility	Age	<u>Sex</u>	Country
16-Feb-2017	13242069	NON-EXPEDITED				US-MYLAN 2016M104				Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	Unk U	lnk, Prn		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242071	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2016M104			13 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	:
Accidental Exposure T Product By Child	o Epiper	n Auto-Injector			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242074	NON-EXPEDITED				US-MYLAN 2016M104	_		7 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
No Adverse Event; Off Label Use	Epiper	n Auto-Injector			S		Unk			Му	vlan .

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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242076	NON-EXPEDITED				US-MYLAN 2016M1052				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	:
Device Failure; Expire	d Epipe	n Auto-Injector			S		Unk			Му	/lan
Product Administered	Epipe	n Auto-Injector			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242077	NON-EXPEDITED				US-MYLAN 2016M1034				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	:
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 N	lg, Once		Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242078	NON-EXPEDITED				US-MYLAN 2016M1039	-		50 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Expired Prod Administered; Injectior Site Pain	uct	n Auto-Injector			S	Intramuscular	0.3 M	lg, Prn		Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2017	13242080	NON-EXPEDITED				US-MYLAN 2016M1033	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	Mfr	:
Pain	Epipe	n Trainer			S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242082	NON-EXPEDITED				US-MYLAN 2016M1057			305 DAY	Female	USA



Preferred Term	Prod	uct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Injection Site Bruising; Injury Associated With Device		en Jr. Auto-Injector dryl /00000402/			S C	Intramuscular Oral	0.15 Mg, Prn Unk, Prn		-	rlan rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242108	NON-EXPEDITED				US-MYLAN 2016M1035			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242114	NON-EXPEDITED				US-MYLAN 2016M1033	=	64 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242122	NON-EXPEDITED				US-MYLAN 2016M1034		41 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure	Epipe	en Auto-Injector			S	Subcutaneous	0.3 Mg, Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2017	13242132	NON-EXPEDITED				US-MYLAN 2016M1034	_	19 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Unk		Му	rlan



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
21-Feb-2017	12723898	EXPEDITED (15-DAY)			DE	GB-MYLANLA 2016M103810	_			Unknown	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Allergy To Arthropod Sting; Device Breakag Device Failure; Device Malfunction; Dyspnoea					S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Feb-2017	13256482	DIRECT	Υ		HO, RI					Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Device Malfunction	Epineph Injector)	nrine (Epipen Auto-			S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Feb-2017	13264082	DIRECT	Υ		HO, LT, OT				17 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	ОТС	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Injury; Vascular Pseudoaneurysm	Epipen				S	Intramuscular				М	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2017	13235496	EXPEDITED (15-DAY)			HO, OT	US-PFIZER IN 2017060587	NC-		55 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Dyspnoea; Hypotensic Oxygen Saturation Decreased; Pharyngea Oedema; Wrong Technique In Product Usage Process					S		Unk			Pi	iizer



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2017	13264351	EXPEDITED (15-DAY)		C	T	US-PFIZER II 2017072010	NC-		53 YR	Male	USA
Preferred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Accidental Exposure T Product; Injection Site Pain; Needle Issue; Product Quality Issue		pipen			S	Intramuscular	0.3 Mg	g, Once			Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
24-Feb-2017	13269103	EXPEDITED (15-DAY)		C	T	JP-PFIZER IN 2014165887	NC-		10 YR	Male	JPN
Preferred Term	<u>Pr</u>	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>N</u>	<u>Mfr</u>
Accidental Evaceure T		inan Λ 15ma									
Accidental Exposure T Product By Child; Haemorrhage Subcutaneous; Injection Site Bruising; Injection Discolouration	on .	oipen 0.15mg			S	Subcutaneous	Unk				Pfizer
Product By Child; Haemorrhage Subcutaneous; Injectic Site Bruising; Injection	on Site	oipen 0.15mg <u>Case Type</u>	<u>Health</u>	Prof C	Outcomes	Subcutaneous  Mfr Control		503B Facility	<u>Age</u>	<u>Sex</u>	Country
Product By Child; Haemorrhage Subcutaneous; Injectic Site Bruising; Injection Discolouration	on Site	Case Type	Health					503B Facility	<u>Age</u>		Country
Product By Child; Haemorrhage Subcutaneous; Injection Site Bruising; Injection Discolouration  FDA Received Date	on Site Case # 13274772	Case Type	Health Comp.		Outcomes	Mfr Control ZA-MYLANLA		•	Age Duration	Sex Unknow	Country
Product By Child; Haemorrhage Subcutaneous; Injectic Site Bruising; Injection Discolouration  FDA Received Date 27-Feb-2017	Case # 13274772 Pr	Case Type  EXPEDITED (15-DAY)		C	<b>Dutcomes</b> DT	Mfr Control ZA-MYLANLA 2017M100936	# ABS- 69	•		Sex Unknow	<b>Country</b> n ZAF
Product By Child; Haemorrhage Subcutaneous; Injectic Site Bruising; Injection Discolouration  FDA Received Date 27-Feb-2017  Preferred Term  Device Failure; Product	Case # 13274772 Prot Ep	Case Type EXPEDITED (15-DAY) Coduct Dipen (Epinephrine) Auto	Comp.	<u>otc</u>	Outcomes OT Role	Mfr Control ZA-MYLANLA 2017M100936	# ABS- 69 <b>Dosage</b> Unk	•		Sex Unknow	Country  n ZAF
Product By Child; Haemorrhage Subcutaneous; Injectic Site Bruising; Injection Discolouration  FDA Received Date 27-Feb-2017  Preferred Term  Device Failure; Product Quality Issue	Case # 13274772 Prot Ep	Case Type  EXPEDITED (15-DAY)  Coduct  Dippen (Epinephrine) Auto ector 0.3 Mg  Case Type	Comp.	<u>otc</u>	Outcomes OT Role S	Mfr Control ZA-MYLANLA 2017M100936 Route	# ABS 69 <b>Dosage</b> Unk	e Text	<u>Duration</u>	Sex Unknown	Country  n ZAF  Mfr  Mylan
Product By Child; Haemorrhage Subcutaneous; Injection Site Bruising; Injection Discolouration  FDA Received Date 27-Feb-2017  Preferred Term  Device Failure; Produc Quality Issue  FDA Received Date	Case #  13274772  Pr  ct Ep Inj  Case #  13241288	Case Type  EXPEDITED (15-DAY)  Coduct  Dippen (Epinephrine) Auto ector 0.3 Mg  Case Type	Comp.	<u>otc</u>	Outcomes OT Role S	Mfr Control ZA-MYLANLA 2017M100936 Route  Mfr Control US-PFIZER II	# ABS 69 <b>Dosage</b> Unk	503B Facility	<u>Duration</u>	Sex Unknown Sex Female	Country  Afr  Mylan  Country



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Mar-2017	13285078	EXPEDITED (15-DAY)		0	Т	ZA-MYLANI 2017M1009				Unknown	ZAF
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Issue; Needle Issue		(Epinephrine) Auto 0.3 Mg			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Mar-2017	13288274	EXPEDITED (15-DAY)		Ľ	Г, ОТ	US-MYLANI 2017M1012				Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure; Produc Use Issue	• •	Auto-Injector Auto-Injector			S S	Intramuscular	0.3 Mg	g, Once		Myl Myl	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Mar-2017	13297631	NON-EXPEDITED				US-PFIZER 2017091652				Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Skeletal Injur Wrong Technique In Product Usage Proces	y;				S		Unk			Unl	known
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Mar-2017	13307800	EXPEDITED (15-DAY)		0	т	CA-MYLANI 2017M1013				Unknown	CAN
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Peripheral Swelling	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Mar-2017	13288366	EXPEDITED (15-DAY)		0	Т	AU-MYLANI 2017M1012				Unknown	AUS



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Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	[
Drug Ineffective; Inject Site Pain; Product Qua Issue					S	Intramuscular			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Mar-2017	13321590	EXPEDITED (15-DAY)		0	Т	CA-PFIZER 2017103994			Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	1
Joint Swelling; Periphe Swelling	eral Epipen Epipen				S S	Intramuscular	0.3 Mg, Unk			izer izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Mar-2017	13299814	EXPEDITED (15-DAY)		0	Т	US-PFIZER 2017094172		10 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Hypoaesthesia; Injection Site Movement Impairment; Injection S Nerve Damage; Injecti Site Pain; Injection Site Pallor; Injection Site Reaction	on Site on				S		0.3 Mg, Unk		Pfi	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
13-Mar-2017	13329808	NON-EXPEDITED				US-PFIZER 2017105896		71 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	[
Feeling Jittery;	Epipen				S	Intramuscular	0.3 Mg, Prn		Pfi	izer
Nervousness; Wrong Technique In Device	Epipen Zyrtec				S C		Unk		Pfi	izer
Usage Process	Levocet	tirizine			С		Unk			



							Detailed	(cpoit	ı			
		Hydroxy	zine			С		Unk				
		Hydroxy	zine			С						
FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof Ou	ıtcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
13-Mar-2017	13329	919	NON-EXPEDITED				US-PFIZER 2017106078			81 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>M</u> 1	<u>fr</u>
Accidental Exposure T Product; Expired Product; Administered; Injection Site Bruising; Injection Pain	uct า	Epipen Coumad	din /00014802/			S C		Unk Unk			Р	fizer
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Mar-2017	13333	351	NON-EXPEDITED				US-PFIZER 2017105881				Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Gait Disturbance		Epipen				S		Unk l	Unk, Once		Р	fizer
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Mar-2017	131598	800	EXPEDITED (15-DAY)		01	-	US-MYLANI 2017M1005				Unknown	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Accidental Exposure T		Epipen .	Jr. Auto-Injector			S		0.15	Mg, Unk		M	lylan
Product; Expired Production Administered; Injection		Sertralir	ne			С	Oral	100 N	Mg, Qd		M	lylan
Site Hypoaesthesia; njection Site Pain; Inju		Sertralir Venlafa				C C	Oral	75 M	g, Qd			lylan Iylan
Associated With Devic Motor Dysfunction; Ne Issue; Neuralgia; Skele	edle	Venlafa Alprazo				C C		Unk				lylan Iylan
njury; Tremor	ciai	Alprazo Aspirin	lam /00002701/			C C		Unk				lylan Iylan
		Meclizin	e /00072801/			С	Oral	25 M	g, Tid		M	lylan
		Meclizin	ne /00072801/			С					M	lylan

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Meclizine /00072801/ Omeprazole Vitamin D /00107901/		azole			C C	Oral Oral	20 Mg, 1000 N	, Qd I/A, Qd		Myl Myl Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	<u>N</u>	Ifr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Mar-2017	13347352	EXPEDITED (15-DAY)			ОТ		B-MYLANLABS- 017M1016934			Unknown	GBR
Preferred Term	Term Product		Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Malfunction; Epipen (Epinephrine) Auto njection Site Pain; Injury Injector 0.3 Mg Associated With Device				S		Unk			Myl	an	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	<u>N</u>	Ifr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Mar-2017	13351101	NON-EXPEDITED				_	S-PFIZER INC- 017119649	NC-		Unknown	USA
Preferred Term	erred Term Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain	Epipen		S			Unk			Pfizer		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	<u>N</u>	Ifr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Mar-2017	13361242 EXPEDITED (15-DAY)		ОТ			JP-MYLANLABS- 2017M1018049				Unknown	JPN
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Use Issue; Needle Epipen Issue			S					Mylan			
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	<u>N</u>	Ifr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Mar-2017	13361267	EXPEDITED (15-DAY)	DE, OT			AU-MYLANLABS- 2017M1017795			Unknown	AUS	
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Drug Ineffective	r; Drug Ineffective Epipen				S	Intramu	scular			Myl	an



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	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Mar-2017	13272954	EXPEDITED (15-DAY)			ОТ	GB-PFIZER IN 2017083172	C-	15 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Accidental Exposure To Product; Injection Site Coldness; Injection Site Ischaemia; Injection Site Pallor; Pain; Paraesthe	e te				S		0.3 Mg, Unk (0.3 Mg Of 1:1000 From An Epipen)		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Mar-2017	13364016	EXPEDITED (15-DAY)			ОТ	CA-PFIZER IN 2017120389	C-	9 YR	Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product By Child; Inject Site Coldness; Injection Site Ischaemia; Injection	tion n				S		0.3 Mg Of 1:1000 Epinephrine		Pti	zer
Site Pain; Injection Site Pallor; Injection Site Paraesthesia										
Site Pain; Injection Site Pallor; Injection Site	9	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	<u> 503B Facility</u>	Age	<u>Sex</u>	Country
Site Pain; Injection Site Pallor; Injection Site Paraesthesia	9	Case Type EXPEDITED (15-DAY)	Health		Outcomes HO, OT	Mfr Control # JP-MYLANLAB 2017M1018051	3S-	Age	<u>Sex</u> Unknown	<u>Country</u> JPN
Site Pain; Injection Site Pallor; Injection Site Paraesthesia  FDA Received Date	Case #	EXPEDITED (15-DAY)	Health Comp.		HO, OT	JP-MYLANLAB	3S-	Age  Duration		JPN
Site Pain; Injection Site Pallor; Injection Site Paraesthesia  FDA Received Date  23-Mar-2017	Case # 13366064  Produc  Epipen	EXPEDITED (15-DAY)			HO, OT	JP-MYLANLAB 2017M1018051	3S- 1		Unknown Mfr	JPN
Site Pain; Injection Site Pallor; Injection Site Paraesthesia  FDA Received Date 23-Mar-2017  Preferred Term  Device Failure; Expired Product Administered; Injection Site Bruising; Needle Issue; Product	Case # 13366064  Product  Epipen	EXPEDITED (15-DAY)	Comp.	OTC	HO, OT	JP-MYLANLAB 2017M1018051	Dosage Text Unk		Unknown Mfr	JPN



Preferred Term	Produc	<u>&gt;t</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Pallor; Periph Coldness					S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2017	13377168	EXPEDITED (15-DAY)		C	DΤ	JP-MYLANL 2017M1019				Unknown	JPN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Use Issue; Dru Dose Omission; Needl Issue					S		0.3 Mg	յ, Unk		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2017	13379541	EXPEDITED (15-DAY)		H	Ю	AU-MYLANI 2017M1019	-			Unknown	AUS
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen				S	Intramuscular	300 M	cg, Unk		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Mar-2017	13383270	EXPEDITED (15-DAY)		L	T, OT	US-MYLANI 2017M1018	-			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Mar-2017	13384365	EXPEDITED (15-DAY)		L	T, OT	CA-MYLANI 2017M1019				Unknown	CAN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Jr			S	Intramuscular	Unk			Myl	an



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	<u>#</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Mar-2017	13391995	NON-EXPEDITED			LT, OT	US-PFIZER IN: 2017139113	C-		16 YR	Female	USA
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	<u>Mfr</u>	
Orug Ineffective	Epipen				S	Intramuscular	0.3 Mg,	Once		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Mar-2017	13393040	EXPEDITED (15-DAY)			ОТ	FR-SA-2017SA	\048383		57 YR	Female	FRA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Cyanosis; Hypoaesthesia; Paraesthesia	To Epipen				S	Intravenous (not otherwise specified)	Dose: 1: Ml; Arou	Form: Infusion 1000 Solution 0.3 nd 80% Of The ose Was Infused			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	<u>ŧ</u>	03B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13395268	DIRECT			DS, HO, LT				18 YR	Female	USA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	<u>Mfr</u>	
Product Quality Issue	Epipen, Quetiapi Vyvanse	ine			S C C	Intramuscular	Quantity	:1 Injection(S);		Myla	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	<u>#</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Apr-2017	13395368	DIRECT			ОТ				30 YR	Female	USA
				0.70	Role	Route	Dosage T	' <u>ext</u>	Duration	<u>Mfr</u>	
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Kole	Noute	<u>Doougo i</u>			<u></u>	
Preferred Term  Orug Ineffective; Produ  Quality Issue		t 2-Pak (Epinephine) Auto-	-	OIC	S S	Intramuscular		:2 Injection(S);		Myla	an
Drug Ineffective; Produ	luct Epipen 2						Quantity	2 Injection(S);	Age		Country

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Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>le Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2017	13394290	EXPEDITED (15-DAY)		(	TC	GB-MYLAN 2017M102	_			Unknown	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Panic Attack; Post-Traumatic Stress Disorder	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Cont	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2017	13394295	EXPEDITED (15-DAY)		(	TC	AU-MYLAN 2017M101	-			Unknown	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen				S	Intramuscular	300 N	Лcg, Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2017	13394296	EXPEDITED (15-DAY)		(	TC	AU-MYLAN 2017M101				Unknown	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>le Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen Injector	(Epinephrine) Auto 0.3 Mg			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cont	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2017	13394401	EXPEDITED (15-DAY)		I	_T, OT	CA-MYLAN 2017M102	_			Unknown	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	



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Device Failure; Intention Product Misuse					S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2017	13394402	EXPEDITED (15-DAY)		ŀ	HO, LT, OT	US-MYLANLA 2017M102059			Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2017	13395570	DIRECT		ŀ	HO, LT			37 YR	Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Malaise; Product Qual Issue; Swelling Face	ity Epipen		Υ		S	Intramuscular				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2017	13395610	DIRECT		ŀ	Ю			21 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Device Malfunction; Hypersensitivity	Epi-Pei	n			S					
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Apr-2017	13395800	DIRECT		(	TC			8 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Malfunction; Ke Scar	eloid Epipen				S				Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Control	# 503B Facility	<u>y Age</u>	<u>Sex</u>	Country
03-Apr-2017	13396070	DIRECT		(	OT			15 YR	Female	USA



Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>	
Device Malfunction	Epi-Pen	Auto Injector			S	Subcutaneous				ľ	Mylan	
	Asthma	Inhaler			С							
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
04-Apr-2017	13361271	EXPEDITED (15-DAY)		ſ	DE, HO	AU-MYLAN 2017M1017	-			Unknown	a AUS	
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>: Text</u>	<b>Duration</b>	<u>N</u>	<u>lfr</u>	
Condition Aggravated;	Epipen				S	Intramuscular	300 M	icrogram, Unk		ľ	Mylan	
Device Issue; Drug Ineffective	Ventolin				S		Unk			ľ	Mylan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
04-Apr-2017	13402571	EXPEDITED (15-DAY)		(	OT	US-MYLAN 2017M1020				Unknown	u USA	
Preferred Term	<u>Produc</u>	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>: Text</u>	<b>Duration</b>	<u>N</u>	<u>lfr</u>	
Apnoea; Device Failure	e Epipen /	Auto-Injector			S		Unk			1	Mylan	
	Cyclobe	nzaprine Hydrochloride			С		5 Mg,	Prn (10 Years)				
	Hydroco Bitartrat	done e/Paracetamol			С		1000 N	Mg, Prn				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
04-Apr-2017	13402573	EXPEDITED (15-DAY)		I	НО	US-MYLAN 2017M1020				Unknown	u USA	
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>: Text</u>	<b>Duration</b>	<u>N</u>	<u>lfr</u>	
Drug Effect Decreased	Epipen .	Jr. Auto-Injector			S		Unk			ľ	Mylan	
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	Sex	Country	
04-Apr-2017	13403572	DIRECT		I	_T				12 YR	Male	USA	
Preferred Term	Produc	t .	Comp.	отс	Role	Route	Dosage	Toyt	Duration	N/	lf <u>r</u>	

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							•				
Product Quality Issue;	Epipen				S	Intramuscular	Quant	ity:1 Injection(S);		My	lan
Therapy Non-Respond	ler Allegra	Odt Children'S			С						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13371052	EXPEDITED (15-DAY)		(	OT	NZ-MYLANL 2017M10184				Unknown	NZL
Preferred Term	Produc	<u>ct</u>	Comp.	<u>otc</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure; Device Use Issue	Epipen				S		Unk			My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13383372	EXPEDITED (15-DAY)		[	DE, HO, OT	AU-PFIZER 2017126254				Female	AUS
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Issue; Drug Ineffective					S S	Intramuscular	300 M Unk	icrogram, Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13406335	EXPEDITED (15-DAY)		ŀ	HO, OT	US-MYLANL 2017M10193				Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure	Epipen	Auto-Injector			S		Unk			My	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13407317	EXPEDITED (15-DAY)		(	DΤ	FR-INTERN. MEDICATIO SYSTEMS, I 10650	N		57 YR	Female	FRA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>otc</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Accidental Exposure To Product; Cyanosis; Hypoaesthesia; Paraesthesia	o Epipen				S						ernational dication System

Note: If the field is blank, there is no data.

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FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13407436	EXPEDITED (15-DAY)		L	T, OT	US-MYLANI 2017M1021	-			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure		n Auto-Injector se /00908302/			s C	Intramuscular	0.3 M Unk, (	g, Prn Qd		Myl Myl	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13407437	EXPEDITED (15-DAY)		L	T, OT	US-MYLANI 2017M1020				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mfr	
Device Failure; Drug D Dmission	ose Epipei	n Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13407438	EXPEDITED (15-DAY)		L	.Т	US-MYLANI 2017M1020				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>	Mfr	
Device Failure; Drug D Dmission; Needle Issu		n Auto-Injector			S	Intramuscular	Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13408229	DIRECT	Υ	[	DΕ				36 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Death	Gamn	nagard Liquid			S		25gm Periph	Every 4 Weeks neral			
	Epipei	n 0.3mg			S		•				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2017	13409246	DIRECT			.Т				2 YR	Male	USA



Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Malfunction	Epipen .	Jr			S	Intramuscu	ar			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr (	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2017	13346724	EXPEDITED (15-DAY)		F	IO, OT		YLANLABS- M1016641			Unknown	AUS
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Issue; Drug Ineffective	Epipen				S		Unk		Mylan		an
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof C	<u>outcomes</u>	Mfr (	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2017	13411924	EXPEDITED (15-DAY)		D	E, OT		IZER INC- 146509			Unknown	IRL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Death	Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr (	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2017	13418861	EXPEDITED (15-DAY)		C	T		YLANLABS- M1021191			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen /	Auto-Injector			S		Unk,	Prn		Myl	an
	Vitamins	s Nos			С		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>outcomes</u>	Mfr (	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2017	13418863	EXPEDITED (15-DAY)		C	T		YLANLABS- M1021183			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen /	Auto-Injector			S		0.3 M	g, Once		Myl	an



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol# <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2017	13418865	EXPEDITED (15-DAY)		LT	, OT	US-MYLANI 2017M1021				Unknown	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epipe Zyrte Qvar				S C C	Intramuscular Oral	0.3 Mg, C Unk, Qd Unk, Bid	Once		Myl Myl Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2017	13418866	EXPEDITED (15-DAY)		0	Γ	US-MYLANI 2017M1021				Unknown	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	Mfr	
Device Failure; Needle Issue	e Epipe	en Jr. Auto-Injector			S	Intramuscular	0.15 Mg,	Prn		My	an
<b>FDA Received Date</b>	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2017	13418867	EXPEDITED (15-DAY)		Н	O, LT, OT	US-MYLANI 2017M1021				Unknown	USA
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage To	<u>ext</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	en Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Apr-2017	13413095	EXPEDITED (15-DAY)		0	Γ	AU-MYLANI 2017M1019	_			Unknown	AUS
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	Mfr	
Device Failure; Device Use Issue; Drug Dose Omission; Product Qu Issue	Injec	en (Epinephrine) Auto tor 0.3 Mg			S		Unk			My	an



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Apr-2017	13415854	NON-EXPEDITED				US-PFIZEF 201714907	-			Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Incorrect Dose Administered; Weight Decreased	Epipe	n			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
07-Apr-2017	13419711	NON-EXPEDITED				US-PFIZEF 201714906	-			Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Skeletal Injur		n			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
07-Apr-2017	13422505	DIRECT	Υ		НО				59 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Effect Decreased		n 2-Pak Auto Injector /0.3ml			S	Intramuscular				Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2017	13364017	EXPEDITED (15-DAY)			ОТ	FR-PFIZEF 201712053	-		57 YR	Female	FRA
Preferred Term	<u>Produ</u>	uct	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Cyanosis; Hypoaesthesia; Paraesthesia	ō Epipe	n			S		Arour	00 Solution 0.3 MI; nd 80% Of The Who (0.3mg/0.3mI)	le	Pfi	zer



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2017	13421855	NON-EXPEDITED			HO, LT, OT	US-PFIZEF 201714907			45 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epiper	ı Jr			S		Unk			Pfiz	zer
	Zyrtec				С	Oral	Unk				
	Monte	ukast			С		Unk				
	Symbi	cort			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2017	13424548	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2017M102	-		Unknown  Duration Mfr		USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Drug Effect Decreased	l Epiper	Auto-Injector			S		0.3 Mg	g, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2017	13424549	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M102	-			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Drug Ineffective	Epiper	Auto-Injector			S		0.3 Mg	g, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2017	13424553	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M102				Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epiper	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2017	13424556	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2017M102				Unknown	USA

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Preferred Term	Produc	t	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Device Failure	; Epipen <i>i</i>	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2017	13424738	NON-EXPEDITED			НО	US-PFIZEF 201714907				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Effect Decreased	Epipen .	Jr			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2017	13176731	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1006	_			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Contusion; Injection Sit Scar; Injury Associated With Device		Jr. Auto-Injector			S	Intramuscular	0.15 N	/lg, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2017	13377165	EXPEDITED (15-DAY)			ОТ	PT-MYLAN 2017M1018				Unknown	PRT
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Dose Omission; Needle Issu					S		0.3 Mg	g, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2017	13382394	EXPEDITED (15-DAY)			DE, HO, OT	AU- GLAXOSM AU2017GS				Female	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Condition Aggravated; Device Issue; Drug Ineffective	Ventolin Epipen (	(Adrenalin)			S S	Intramuscular	300 U	nk, Unk		Gla	axosmithkline



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FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr	Control #	503B Facility	Age	Sex	Country
11-Apr-2017	13417534	EXPEDITED (15-DAY)	Hould		DE, LT, OT	CA-I	PFIZER INC- 147111	ooo raomy	<u> </u>	Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Device Failure; Device Use Issue; Dru Dose Omission; Produ Quality Issue	g				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	<u>Mfr</u>	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2017	13427070	EXPEDITED (15-DAY)		(	ОТ		/YLANLABS- M1021990			Unknown	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen				S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	<u>Mfr</u>	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2017	13427842	NON-EXPEDITED		1	LT, OT		PFIZER INC- 149075			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increa					S		Unk			Pfi	zer
Device Failure; Device Use Issue; Heart Rate Increased; Product Qu Issue	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2017	13427903	NON-EXPEDITED		(	ОТ		PFIZER INC- 149066			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Issue; Drug Dose Omission; Haematoma Product Quality Issue					S		Unk			Pfi	zer



FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol #	503B Facility	Age	Sex	Country
11-Apr-2017	13429270	EXPEDITED (15-DAY)		C	Т	US-MYLAN 2017M1022	_			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mf	<u>.</u>
Drug Ineffective	Epipen	Jr. Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Apr-2017	13429394	EXPEDITED (15-DAY)		F	Ю	US-MYLAN 2017M1022				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mf	<u>r</u>
Device Failure		Jr. Auto-Injector /I /0000402/			S C	Intramuscular	0.15 l 7.5 M	Mg, Once I. Prn			ylan ylan
	Zyrtec				С	Oral	5 MI,			M	ylan
	Multivita	amin /00097801/			С	Oral	1 Df,			M	ylan
	Albutero	ol Hfa			С	Respiratory (inhalation)	2 Puff	s Q4h		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Apr-2017	12927625	EXPEDITED (15-DAY)		L	T, OT	US-MYLAN 2016M1047	_			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mf	<u>r</u>
Device Failure; Injection	on Epipen	Auto-Injector			S	Intramuscular	0.3 M	g/MI, Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Apr-2017	13356864	EXPEDITED (15-DAY)		C	T	JP-MYLAN 2017M1017				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mf	<u>.</u>
Device Use Issue; Pro	duct Epipen				S		Unk			M	ylan
Leakage; Wrong Technique In Product	Epipen				S					M	ylan

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Usage Process											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13430583	NON-EXPEDITED				US-PFIZER II 2017149409	NC-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Injection Site Bruising	Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Apr-2017	13434337	NON-EXPEDITED		Ľ	т, от	US-PFIZER II 2017151292	NC-		60 YR	Female	USA
<u>Preferred Term</u>	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Device Failure; Device Use Issue; Drug Dose Omission; Product Qualssue		Jr			S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Apr-2017	13435361	EXPEDITED (15-DAY)		0	T	US-PFIZER II 2017148972	NC-		52 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Apnoea; Device Failure	e; Epipen				S		Unk			Pfiz	er
Device Issue; Product Quality Issue	Cyclobe	nzaprine Hydrochloride			С		5 Mg, P	rn (10 Years)			
Quality 10000	Acetami Bitartrat	nophen W/Hydrocodone e			С		1000 M	g, Prn			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13402502	EXPEDITED (15-DAY)		D	E, OT	IE-PFIZER IN 2017146556	IC-			Unknown	IRL
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Death	Epipen				S		Unk			Pfiz	er



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13424555	EXPEDITED (15-DAY)		Ľ	T, OT	US-MYLAN 2017M1021			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Device Failure	Epipen	Auto-Injector			S		Unk		My	an
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13434456	EXPEDITED (15-DAY)		Н	O, OT	US-MYLAN 2017M1022			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Prn		My	an
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13436138	NON-EXPEDITED		Ľ	т, от	US-PFIZER 2017153412		14 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen				S	Intramuscular	0.3 Mg, Once		Pfiz	er
	Zyrtec				С	Oral	Unk, Qd			
	Qvar				С		Unk, Bid			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13436140	NON-EXPEDITED		0	т	US-PFIZER 2017153409		27 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen	Jr			S		0.3 Mg, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13436163	NON-EXPEDITED		Н	O, LT, OT	US-PFIZER 2017153964		40 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	



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Drug Ineffective	Epiper	n 0.3mg			S	Intramuscular	0.3 Mg	g, Prn	Pfizer		
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13436165	NON-EXPEDITED				US-PFIZER 2017153407			67 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Malaise; Vomiting	Epiper	١			S		Unk			Pfiz	zer
	Lisino	oril			С		20 Mg	, Qd			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13436167	NON-EXPEDITED		0	Т	US-PFIZER 2017153300			55 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Expir Product Administered; Product Storage Error		n 0.3mg			S	Intramuscular	0.3 Mg	g, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13436170	NON-EXPEDITED		0	Т	US-PFIZER 2017155545			24 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective	Epiper	า			S	Intramuscular	0.3 Mg	g, Once		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13439632	EXPEDITED (15-DAY)		0	Т	US-MYLANI 2017M1022				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epiper	n Auto-Injector			S		0.3 Mg	g, Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13439639	EXPEDITED (15-DAY)		0	т	US-MYLANI 2017M1022				Unknown	USA

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Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	Unk Unk, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13439643	EXPEDITED (15-DAY)		L	T, OT	US-MYLAN 2017M1022			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2017	13439791	EXPEDITED (15-DAY)		(	TC	US-MYLANLABS- 2017M1022866			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Apr-2017	12930269	EXPEDITED (15-DAY)		(	TC	US-PFIZER 201652362		18 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mfr	
Injection Site Laceration Product Quality Issue; Vomiting	, I I				S	Intramuscular	ramuscular 0.3 Mg, Single		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Apr-2017	13428350	EXPEDITED (15-DAY)		Г	DE	CA-PFIZER INC- 2017148908			Unknown	CAN
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	e Route Dosage Text		<b>Duration</b>	<u>Mfr</u>	
Death; Expired Produc Administered	ct Epipen				S		Unk		Pfiz	er



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Apr-2017	13443058	NON-EXPEDITED		C	T	US-PFIZE 201716103			7 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen				S		0.15 N	/lg, Unk		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Apr-2017	13443175	NON-EXPEDITED		L	T, OT	US-PFIZE 20171579				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Drug Effect Decreased	d Epipen (	0.3mg			S		0.3 Mg	g, Unk		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Apr-2017	13445221	EXPEDITED (15-DAY)		D	ÞΕ	US-PFIZE 201715880			30 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>e Text</u>	<b>Duration</b>	Mfr	
Death	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2017	13424544	EXPEDITED (15-DAY)		Ľ	T, OT	US-MYLAI 2017M102				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; Drug D Omission	Dose Epipen /	Auto-Injector			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2017	13446818	NON-EXPEDITED		Н	IO, OT	US-PFIZE 201716517			15 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective	Epipen				S	Intramuscular		g, Prn		D4:	zer

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2017	1344737	1 EXPEDITED (15-DAY)			ОТ	US-MYLANL/ 2017M10231				Unknown	USA
Preferred Term	Ē	<u>Product</u>	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	E	pipen Auto-Injector			S		Unk			Му	lan
	L	isinopril			С		10 Mg	, Qd		Му	lan
	N	1etoprolol			С		50 Mg	, Qd		Му	lan
	P	lbuterol /00139501/			С		1-2 Pu Day	ıffs, 3-4 Times A		Му	lan
	N	Metformin			С		500 M	g, Qd		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2017	1344809	5 EXPEDITED (15-DAY)			HO, LT, OT	US-MYLANL/ 2017M10231				Unknown	USA
Preferred Term	Ē	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Cerebrovascular Accid	dent; E	pipen Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Му	lan
Drug Ineffective	C	Sabapentin			С		600 M	g, Tid		Му	lan
	Т	opiramate			С		200 M			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2017	1344810	4 EXPEDITED (15-DAY)			ОТ	US-MYLANL/ 2017M10234				Unknown	USA
Preferred Term	Ē	Product	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Heart Rate		pipen Auto-Injector			S	Intramuscular	0.3 Mg	g, Unk		Му	lan
Increased; Regurgitati Tachycardia	on; L	yrica			С		225 M	g, Bid		Му	lan
raoriyoarala		00048001/			С		Unk	-		Му	lan
	C	Omeprazole			С		Unk			Му	lan
	N	lexium /01479302/			С		Unk			Му	lan
		Depo Provera			С					My	



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l# 50</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2017	13449003	EXPEDITED (15-DAY)		0	Т	US-MYLANL 2017M10238				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure;	Epipen .	Auto-Injector			S		Unk			Му	lan
Pharyngeal Oedema	Gabape	ntin			С		300 Mg, T	Γid		Му	lan
	Verapar	nil			С		80 Mg, Ti	d		Му	lan
	Metopro	olol			С		200 Mg, C	Qd		Му	lan
	Tramad				С		100 Mg, T	Γid		My	
	Pravasta				С		40 Mg, Qo	d		Му	
	Omepra	zol /00661201/		C 40 Mg, Qd			Му	lan			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>1#</u> 50	03B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2017	13449005	EXPEDITED (15-DAY)		L	Г, ОТ	US-MYLANL 2017M10231				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen /	Auto-Injector			S	Intramuscular	0.3 Mg, O	nce		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l#</u> <u>50</u>	03B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2017	13449006	EXPEDITED (15-DAY)		L	Г, ОТ	US-MYLANL 2017M10231				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen A	Auto-Injector			S	Intramuscular	Unk Unk,	Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>1#</u> 50	03B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2017	13439463	NON-EXPEDITED		L	Г, ОТ	US-PFIZER 2017155544	INC-		45 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug	Epipen				S	Intramuscular	0.3 Mg, O	)nce		Pfiz	zer

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Ineffective; Product

Quality Issue											
FDA Received Date	Case #	Case Type	Health		<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2017	13443061	NON-EXPEDITED		(	OT	US-PFIZE 201715880	-		16 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen	0.3mg			S		0.3 N	Иg, Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2017	13455120	NON-EXPEDITED		(	OT	US-PFIZE 201716358	-		41 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen				S		0.3 N	Mg, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2017	13456269	EXPEDITED (15-DAY)		(	OT	US-MYLAI 2017M102	_			Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>otc</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper Diarrhoea; Loss Of Consciousness; Vomit		Auto-Injector			S	Intramuscular	0.3 N	Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2017	13456270	EXPEDITED (15-DAY)		I	₋T, OT	US-MYLAI 2017M102				Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>otc</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S		Unk	Unk, Once		My	lan
	Epipen Depo-F	Auto-Injector Provera			S C					My My	



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	Age	Sex	Country
18-Apr-2017	13456271	EXPEDITED (15-DAY)	ricatti		OT	US-MYLAI 2017M102	NLABS-	<u>ooob raomy</u>	<u>ngc</u>	Unknown	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Ear Swelling; Swelling	Epipen Lisinopi	Auto-Injector ril			s C		0.3 Mg 20 Mg	յ, Once , Qd		Myl Myl	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2017	13456275	EXPEDITED (15-DAY)			ОТ	US-MYLAI 2017M102	_			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipen	Jr. Auto-Injector			S	Intramuscular	Unk U	nk, Once		My	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2017	13457137	DIRECT			HO, LT				25 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	ОТС	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Hypersensitivity; Pharyngeal Oedema; Product Quality Issue; Swelling Face	Epi Pen Flovent Proair				S C C	Intramuscular	Quanti	ty:2 Injection(S);		Myl	an
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2017	13457230	DIRECT	Υ		ОТ				2 YR	Male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	ОТС	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Malfunction; Dr Dose Omission; Injecti Site Laceration; Needle Issue	on Advair e Allegra	Jr ol Nebulizer			S C C C						



							•				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	12745450	NON-EXPEDITED		0	Т	US-PFIZER 2016422924			42 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Hyperventilati	on Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	13428906	EXPEDITED (15-DAY)		0	Т	JP-MYLANL 2017M10219				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Breakage; Dev Failure; Device Use Is: Drug Dose Omission; Limb Injury					S	Intramuscular	0.3 Mg	յ, Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	13439872	NON-EXPEDITED		Lī	г, ОТ	US-PFIZER 2017155542	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Dose Omission; Product Qual Issue		Jr			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	13455158	NON-EXPEDITED		0	Т	US-PFIZER 2017157953			62 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Injection Si Bruising; Injection Site Haematoma; Injection Pain; Product Quality Issue	te				S		Unk			Pfi:	zer

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	13458109	EXPEDITED (15-DAY)			ОТ	US-MYL 2017M10	ANLABS- 023895			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipe	n Auto-Injector			S		0.3 M	g, Once		Му	lan
	Cetiriz	zine			С		10 Mg	-		Му	lan
	Predn	isone			С		10 Mg	ı, Tid		Му	lan
	Monte	elukast			С		10 Mg	ı, Pm		Му	lan
	Proair	· /00139502/			С		2 Puff	s, Qid		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	13458111	EXPEDITED (15-DAY)			LT, OT	US-MYL 2017M10	ANLABS- 023899			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipe	n Auto-Injector			S		0.3 M	g, Once		Му	lan
	Cetiriz	zine			С		10 Mg	ı, Qd		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	13458112	EXPEDITED (15-DAY)			DS, HO, OT	US-MYL 2017M10	ANLABS- 023520			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Cerebrovascular Accid	dent; Epipe	n Auto-Injector			S		0.3 M	g, Once		Му	lan
Seizure	Regla	n /00041901/			S		Unk	•		Му	lan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	13458123	EXPEDITED (15-DAY)			HO, OT	US-MYL 2017M10	ANLABS- 023902			Unknown	USA
<u>Preferred Term</u>	Produ	<u>uct</u>	Comp.	OTC	<u>Role</u>	Route	<u>Dosage</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug Ineffective; Product	Epipe	n Auto-Injector			S	Intramuscular	Unk U	Ink, Once		Му	lan



Storage Error	Hydrox	xyzine			С		10 N	lg, Prn		Myl	an
	Albute	rol Sulfate			С			Mg, Prn		Myl	an
	Spiron	olactone			С		50 N	lg, Qd		Myl	an
	Famoti	dine			С		20 N	lg, Bid		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Apr-2017	13459381	EXPEDITED (15-DAY)			LT, OT	US-MYLANI 2017M1023				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 N	Иg, Prn		Myl	an
	Levoth	yroxine			С		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2017	13439641	EXPEDITED (15-DAY)			LT, OT	CA-MYLANI 2017M1022				Unknown	CAN
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosa	g <u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen				S		0.3 N	Mg, Once		Myl	an
	Benad	ryl /00000402/			S	Intramuscular	25 N	lg, Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2017	13446794	EXPEDITED (15-DAY)			ОТ	JP-MYLANL 2017M1023				Unknown	JPN
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Product Us Issue		(Epinephrine) Auto r 0.3 Mg			S		0.3 N	Mg, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2017	13452173	EXPEDITED (15-DAY)			ОТ	CZ-MYLANI 2017M1023				Unknown	CZE
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosa	ge Text	<u>Duration</u>	Mfr	



Device Failure; Needle Issue	e Epiper	ı			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2017	13460413	NON-EXPEDITED		L	T, OT	US-PFIZER 2017163121			26 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>le Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epiper	n Jr			S	Intramuscular	0.3 N	lg, Once		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2017	13460424	NON-EXPEDITED		C	T	US-PFIZER 2017165743	-		44 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epiper	n			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2017	13461869	EXPEDITED (15-DAY)		C	T	US-PFIZER 2017165151				Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mfr	
Pulmonary Embolism;	Epiper	ı			S		Unk			Pfi	zer
Thrombosis	Humira	a			S	Subcutaneous	Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2017	13461885	EXPEDITED (15-DAY)		C	T	US-MYLAN 2017M1023				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective;		n Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		-	lan
Hypersensitivity; Prurit Generalised; Rash	Metioi				С		5 Mg	, Qd		-	lan
Generalised; Skin	Insulin	bide Mononitrate			C C		22.5				rlan rlan
Discolouration		00109201/			С		30 M	-		-	rlan
	AUVII /	00109201/			<u> </u>		250 N	/lg, Qd		iviy	iaii

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Note: If the field is blank, there is no data.

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	Vitamii	Vitamin E /00110501/ Sucralfate			S		40 Mg	, Qd		Му	/lan
	Sucral	fate			С		1 Df, C	ld		My	/lan
	Losarta	an			С		100 M	g, Qd		My	<i>r</i> lan
	Aspirin	/00002701/			С		350 M	g, Qd		My	⁄lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Apr-2017	13464891	EXPEDITED (15-DAY)		1	ОТ	US-MYLAN 2017M1023	-			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug Ineffective; Wrong Technique In Device Usage Process	Epiper	Auto-Injector			S	Intramuscular	0.3 Mg	ı, Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2017	13465989	NON-EXPEDITED			LT, OT	US-PFIZER 2017170603			65 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective	Epiper	1			S	Intramuscular	0.3 Mg	ı, Once		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2017	13465991	NON-EXPEDITED		1	ОТ	US-PFIZER 201717054				Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Orug Ineffective	Epiper	ı			S		Unk			Pfi	zer
	Levem	ir			С		23 Uni	ts			
	Humal	og			С		3-6 Un	its Before Meals			
	Vyvans	se			С		60 Mg	, Qd			
	Mantal	ukast			С		10 Mg				



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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol # 5	03B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2017	13468474	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2017M1023				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg, C	Once		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol # <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2017	13468475	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1024				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure		n Auto-Injector cet /00446701/			s C	Intramuscular	Unk Unk,			-	rlan rlan
	Zanaf				С		7.5 Mg, T 2 Mg, Bid			-	/lan
	Ateno	lol			С		25 Mg, Q			Му	<i>r</i> lan
	Levot	hyroxine			С		0.25 Mg,			Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol # <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2017	13468477	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1024				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	Mfr	
Drug Ineffective	Epipe	n Auto-Injector			S		0.3 Mg, C	Once		Му	<i>r</i> lan
	Nuvar	ring			С		0.015 Mg	ı, Qd		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol # <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2017	13468510	EXPEDITED (15-DAY)			HO, LT, OT	US-PFIZER 201717045				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accid Drug Ineffective; Hypo	vio	n pentin			s C	Intramuscular	0.3 Mg, C			Pfi	zer



	Topiramate  DA Received Date				С		200 Mg, Bid			
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2017	13468708	EXPEDITED (15-DAY)		(	TC	US-PFIZER IN 2017170538	IC-	43 YR	Female	USA
Preferred Term	<u>Pı</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>!</u>	<u>Mfr</u>
Device Failure; Device		pipen			S		Unk			Pfizer
Use Issue; Needle Issu Pharyngeal Oedema	ie; Ga	abapentin			С		300 Mg, Tid			
Tharyngour Godoma	Ve	erapamil			С		80 Mg, Tid			
	Me	etoprolol			С		200 Mg, Qd			
	Tr	ramadol			С		100 Mg, Tid			
	Pravastatin				С		40 Mg, Qd			
	Oı	meprazol /00661201/			С		40 Mg, Qd			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Apr-2017	13469235	EXPEDITED (15-DAY)		(	OT	US-PFIZER IN 2017172507	IC-	56 YR	Male	USA
Preferred Term	<u>Pı</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>!</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea; Loss Of Consciousness; Vomitin	•	pipen			S	Intramuscular	0.3 Mg, Prn			Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
24-Apr-2017	13418860	EXPEDITED (15-DAY)		l	₋T, OT	US-MYLANLA 2017M102154	=		Unknow	n USA
Preferred Term	<u>Pı</u>	roduct	Comp.	<u>otc</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>!</u>	<u>VIfr</u>
Device Failure; Drug Do	ose Ep	pipen Auto-Injector			S		Unk			Mylan
Omission		pipen Auto-Injector pipen Auto-Injector			S S					Mylan Mylan



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Apr-2017	13472778	NON-EXPEDITED			ОТ	US-PFIZER 2017170540	-		68 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<b>Duration</b>	Mfr	
Device Failure; Device	Epipen				S		Unk			Pfi	izer
Use Issue; Drug Dose Omission; Injection Site	Benicar				С		5 Mg	g, Qd			
Haemorrhage; Injection	n Janume	et			С		50-1	00mg, Bid			
Site Laceration; Produ Quality Issue; Wrong Technique In Product Usage Process	ct Glipizde	•			С		Unk	-			
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Apr-2017	13472779	NON-EXPEDITED			ОТ	US-PFIZER 2017172508			48 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	Mfr	<u>-</u>
Device Failure; Device Use Issue; Injection Si Pain; Product Quality Issue; Underdose		0.3mg			S	Intramuscular	Unk	Unk, Once		Pfi	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Apr-2017	13472781	NON-EXPEDITED			LT, OT	US-PFIZER 2017170602			48 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	ge Text	<u>Duration</u>	Mfr	<u>:</u>
Device Failure; Device Use Issue; Drug Dose Omission; Product Qualssue					S	Intramuscular	Unk	Unk, Once		Pfi	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13472803	EXPEDITED (15-DAY)			DS, HO, OT	US-PFIZER 2017174040			32 YR	Female	USA
, -											



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Cerebrovascular Accid Seizure	,	n n /00041901/			S			g, Once		Pfiz	zer
FDA Received Date		Case Type	Hoolth	Drof	S Outcomes	Mfr Contro	Unk	503B Facility	Ago	Sov	Country
			пеанн					503B Facility	Age	<u>Sex</u>	
24-Apr-2017	13473148	NON-EXPEDITED			LT, OT	US-PFIZER I 2017174919	NC-		55 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipe	n 0.3mg			S	Intramuscular	0.3 Mg	յ, Prn		Pfiz	zer
	Levot	nyroxine			С		Unk				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Apr-2017	13473761	EXPEDITED (15-DAY)			ОТ	CA-MYLANL 2017M10246				Unknown	CAN
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipe	n			S		Unk		Mylan		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Apr-2017	13473764	EXPEDITED (15-DAY)			LT, OT	US-MYLANL 2017M10242				Unknown	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective	Epipe	n Auto-Injector			S		0.3 Mg	g, Once		My	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Apr-2017	13474307	NON-EXPEDITED				US-PFIZER I 2017172937	NC-			Female	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	Mfr	
Malaise	Epipe	n			S		Unk		Pfizer		
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Apr-2017	13474595	EXPEDITED (15-DAY)			ОТ	US-PFIZER I 2017176247	NC-		58 YR	Female	USA

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Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	<u>'r</u>
Drug Ineffective;		n 0.3mg			S	Intramuscular	0.3 Mg	g, Prn		Pf	fizer
Hypersensitivity; Prurit Generalised; Rash	us Vitami	n E /00110501/			С		40 Mg	-			
Generalised; Rash Generalised; Skin	Metfor	min			С		5 Mg,				
Discolouration	Insulin				С		Unk				
	Isosori	oide Mononitrate			С		30 Mg	ı, Qd			
	Advil /	00109201/			С		250 M	lg, Qd			
	Sucral	fate			С		1 Df, 0	Qd			
	Losart	an			С		100 M	lg, Qd			
	Aspirir	/00002701/			С		350 M	lg, Qd			
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Apr-2017	13457084	NON-EXPEDITED			ОТ	US-PFIZER 201717044	-		54 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>'r</u>
Accidental Exposure T Product; Back Disorde Device Failure; Device Use Issue; Injection Si Haemorrhage; Product Quality Issue	r; te	n 0.3mg			S	Intramuscular	0.3 M <sub>(</sub>	g, Prn		Pf	fizer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Apr-2017	13477121	EXPEDITED (15-DAY)			ОТ	US-PFIZER 201717293			40 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Drug Ineffective; Ear	Epiper	n 0.3mg			S		0.3 M	g, Once		Pf	fizer
Swelling; Swelling	Lisinop	oril			С		20 Mg	-			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Apr-2017	13478521	NON-EXPEDITED			HO, OT	US-PFIZER 2017174038			46 YR	Female	USA



Preferred Term	Produc	ct	Comp.	OTC	Role	Route	Dosage	Text	Duration	M1	fr
Device Failure; Device	Epipen	_			S						fizer
Use Issue; Drug						Intramuscular	Once			ŗ	IIZei
Ineffective; Product	Hydrox	•			С		10 Mg				
Quality Issue; Product Storage Error		ol Sulfate			С		1.25 M	lg, Prn			
Storage Error	Spirono	olactone			С		50 Mg	, Qd			
	Famoti	dine			С		20 Mg	, Bid			
FDA Received Date Cas	e #	Case Type	Health	Prof Ou	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Apr-2017 1347	78610	NON-EXPEDITED		0	Γ	US-PFIZER 2017176209			9 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>M1</u>	<u>fr</u>
Device Failure; Device Use Issue; Oral Disorder; Product Quality Issue	Epipen				S		Unk			Р	fizer
FDA Received Date Cas	e #	Case Type	Health	Prof Ou	<u>utcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Apr-2017 1347	78860	NON-EXPEDITED		LT	, ot	US-PFIZER 2017153374			17 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u> 1	<u>fr</u>
Device Failure; Device	Epipen				S		Unk			Р	fizer
Jse Issue; Drug Dose	Epipen				S					Р	fizer
Omission; Product Quality ssue	Epipen				S						fizer
FDA Received Date Cas	e #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Apr-2017 1348	35429	NON-EXPEDITED		0	Γ	US-PFIZER 2017174039				Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u> 1	<u>fr</u>
Drug Ineffective	Epipen				S		0.3 Mc	g, Once		Р	fizer
	Cetirizi	ne			С		10 Mg	-			
	Prednis	sone			С		10 Mg				
							10 IVIQ				

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	Proair /00139502/  PA Received Date				С		2 Puf	fs, Qid			
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Apr-2017	13485479	NON-EXPEDITED		L	_T, OT	US-PFIZER 2017174042	NC-		15 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Drug Ineffective	Epipen				S		0.3 M	lg, Once		Pfiz	er
	Cetirizir	e			С		10 M	g, Qd			
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Apr-2017	13484551	NON-EXPEDITED		L	_T, OT	US-PFIZER 2017181135	NC-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen				S		0.3 M	lg, Once		Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Apr-2017	13486250	EXPEDITED (15-DAY)		H	HO, LT	NL-MYLANL 2017M10255				Unknown	NLD
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Device Malfunction; Di Ineffective; Dyspnoea	rug Epipen	Auto-Injector			S					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Apr-2017	13486262	EXPEDITED (15-DAY)		ŀ	HO, OT	US-MYLANL 2017M10249				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Device Failure; Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular 0.3 Mg, Once Mylan		an			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Apr-2017	13486273	EXPEDITED (15-DAY)		L	_T	US-MYLANL 2017M10249				Unknown	USA



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						Detailed	report				
Preferred Term	Produc	t	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; Drug D Omission; Wrong Technique In Product Usage Process	Dose Epipen /	Auto-Injector			S		0.3 Mg	g, Unk		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13473778	EXPEDITED (15-DAY)		C	T	US-PFIZEF 201717624			49 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective; Injecti Site Haemorrhage	tion Epipen	Jr			S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Apr-2017	13489404	EXPEDITED (15-DAY)		Н	IO, OT	US-PFIZEF 201718074	_		17 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Injection Site Bruising; Injection Site Swelling; Limb Mass; Pain In Extremity; Vascular Pseudoaneurysm; Yell Skin	;				S	Intramuscular	0.3 Mg	g, Prn		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Apr-2017	13490584	EXPEDITED (15-DAY)		C	T	US-MYLAN 2017M1024				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen A	Auto-Injector			S		0.3 Mg	g, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
					T	US-PFIZEF	NC-		39 YR	Female	USA
27-Apr-2017	13492247	NON-EXPEDITED		C	<b>/</b> 1	201717869			39 TK	Temale	UUA



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Drug Ineffective					S		0.3 Mg, Once	Pfizer			
	Benad	dryl /00000402/			S		1 Df, Once				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
27-Apr-2017	13495279	DIRECT		I	DE			31 YR	Male	USA	
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	<u>.</u>	
Death	Epi-Pe	en			S	Intramuscular			Me	eridian	
	Breo Albute	erol Inhalers			C C						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
28-Apr-2017	13494779	NON-EXPEDITED		(	ОТ	US-PFIZER IN 2017181168	C-	43 YR	Female	USA	
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfı</u>	<u>r</u>	
Drug Ineffective; Inject		n 0.3mg			S		0.3 Mg, Once		Pf	izer	
Site Bruising; Injection Erythema; Injection Sit Paraesthesia; Injection Site Warmth	te						0.5 Mg, Office				
Erythema; Injection Sit Paraesthesia; Injection Site Warmth	te	Case Type	Health	Prof (	Outcomes	Mfr Control #		Age	<u>Sex</u>	<u>Country</u>	
Erythema; Injection Sit Paraesthesia; Injection Site Warmth	te า	Case Type  NON-EXPEDITED	Health			Mfr Control # US-PFIZER IN 2017178578	<u> 503B Facility</u>	Age 30 YR	<u>Sex</u> Female		
Erythema; Injection Sit Paraesthesia; Injection Site Warmth  FDA Received Date	te n <u>Case #</u>	NON-EXPEDITED	Health		<u>Outcomes</u>	US-PFIZER IN	<u> 503B Facility</u>			<u>Country</u> USA	
Erythema; Injection Sit Paraesthesia; Injection Site Warmth  FDA Received Date 28-Apr-2017	te Case # 13494829 <u>Produ</u>	NON-EXPEDITED		(	Outcomes OT	US-PFIZER IN 2017178578	<b>503B Facility</b>	30 YR	Female	<u>Country</u> USA	
Erythema; Injection Sit Paraesthesia; Injection Site Warmth  FDA Received Date 28-Apr-2017  Preferred Term  Drug Ineffective; Feelin Hot; Paraesthesia;	Case # 13494829  Produ	NON-EXPEDITED	Comp.	<u>OTC</u>	Outcomes OT Role S	US-PFIZER IN 2017178578	503B Facility C-  Dosage Text  0.3 Mg, Once 0.015 Mg, Qd	30 YR	Female	<u>Country</u> USA	
Erythema; Injection Sit Paraesthesia; Injection Site Warmth  FDA Received Date 28-Apr-2017  Preferred Term  Drug Ineffective; Feelin Hot; Paraesthesia; Paraesthesia Oral	te n Case # 13494829 Produ ng Epiper Nuvar	NON-EXPEDITED  uct  n ing	Comp.	OTC Prof	Outcomes OT Role S C	US-PFIZER IN 2017178578 Route Intramuscular	503B Facility C-  Dosage Text  0.3 Mg, Once 0.015 Mg, Qd  503B Facility 3S-	30 YR  Duration	Female <u>Mf</u> ı Pf	Country USA I	



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Device Failure	Epipen	Auto-Injector			S		0.3 Mg,	Once		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Control	<b>#</b>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Apr-2017	13496788	NON-EXPEDITED		C	T	US-PFIZER II 2017178579	NC-		21 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage <sup>-</sup>	<u>Text</u>	<u>Duration</u>	Mf	<u>r</u>
Device Failure; Device					S		Unk			Pf	izer
Use Issue; Drug Effect Incomplete; Product	Rifabuti	n			С		Unk				
Quality Issue	Xarelto				С		20 Mg, (	Qd			
	Trilepta				С		100 Mg,				
	Cipro /0	0697201/			С						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Apr-2017	13497158	EXPEDITED (15-DAY)		C	T	US-PFIZER II 2017187812	NC-		45 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage <sup>-</sup>	<u>Text</u>	<b>Duration</b>	Mf	<u>r</u>
Accidental Exposure T Product; Device Failure Device Use Issue; Injection Site Discolouration; Injectio Site Hypoaesthesia; Product Quality Issue	e;				S	Intramuscular	Unk Unl	k, Once		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
28-Apr-2017	13497319	EXPEDITED (15-DAY)		C	T	US-MYLANL/ 2017M10254				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage <sup>*</sup>	<u>Text</u>	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg,	Prn		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Apr-2017	13497685	NON-EXPEDITED		F	IO, OT	US-PFIZER II 2017185369	NC-		59 YR	Male	USA

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Preferred Term	Product	į.	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	Epipen				S	Intramuscular	0.3 Mg, Once		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Apr-2017	13497757	EXPEDITED (15-DAY)		Н	O, LT	NL-PFIZER 2017186876			Female	NLD
Preferred Term	Product	<u> </u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Device Malfunction; Device Use Issue; Drug Ineffective; Dyspnoea; Product Quality Issue	Epipen (	).3mg			S		Unk		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2017	13472782	NON-EXPEDITED		0	Т	US-PFIZER 2017170542	=	59 YR	Female	USA
Preferred Term	Product	1	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Use Error; Drug Ineffective; Product Quality Issue	Epipen 0	).3mg			S	Intramuscular	0.3 Mg, Once		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2017	13500494	NON-EXPEDITED		0	Т	US-PFIZER 2017180955			Female	USA
Preferred Term	Product	<u>I</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Device Failure; Device Use Issue; Drug Dose Omission; Rash	Epipen				S		Unk Unk, Once		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2017	13500602	NON-EXPEDITED		D	E, OT	US-PFIZER 2017189935	INC-		Female	USA



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Preferred Term	Pro	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epip	pen			S		Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2017	13500604	NON-EXPEDITED		1	ОТ	US-PFIZEF 201718772	=		Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epip	oen 0.3mg			S	Intramuscular	0.3 Mg, Prn		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Conti	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-May-2017	13500609	NON-EXPEDITED				US-PFIZEF 201719013		4 YR	Male	USA
Preferred Term	<u>Pro</u>	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product By Child	o Epip	oen Jr			S	Intramuscular	Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-May-2017	13456273	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M102			Unknown	USA
Preferred Term	<u>Pro</u>	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug Ineffective	Epip	oen Auto-Injector			S		Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-May-2017	13504439	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2017M102			Unknown	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D	ose Epip	oen Auto-Injector			S	Intramuscular	Unk Unk, Once		Му	lan
Omission	Cro	moglicate Sodium			С	Oral	Unk			
	Diph	nenhydramine			С		Q2-4h			
	Alur	ninium Hydroxide Gel,			С		40 Mg, Qd			



						Dotalica	topo.t				
		l/Magnesium Carbonate xetine Hydrochloride			С		30 Mg	, Unk			
	Salbu	utamol			С		Unk, G	ld			
		opium			C						
	Pred	nisone			С		Unk, C	)d			
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-May-2017	13504441	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1025				Unknown	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Expir	ed Epipe	en Jr. Auto-Injector			S	Intramuscular	0.15 N	la. Prn		Му	lan
Product Administered	Epipe	en Jr. Auto-Injector			S			3,		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-May-2017	13507960	NON-EXPEDITED			ОТ	US-PFIZER 2017189815			41 YR	Female	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epipe	en			S		Unk			Pfi	zer
	Epipe	en			S		Unk			Pfi	zer
	Azith	romycin			С		Unk, G	ld			
	Doxy	cline /00055701/			С		200 M				
	Plaqı	uenil /00072602/			С		Unk, G				
	Нера	arin			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-May-2017	13513907	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1026				Unknown	USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg	յ, Prn		Му	lan
	Hydra	alazine			С		25 Mg			Му	lan
	Losa	rtan			С		10 Mg			Му	lan

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							•				
	Amlodipine Carvedilol				С		10 Mg,	Qd		Му	lan
	С	arvedilol			С		25 Mg,	Bid		Му	lan
	M	etformin			С		500 Mg	g, Bid		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-May-2017	13514508	B EXPEDITED (15-DAY)		I	T, OT	US-MYLANI 2017M1025				Unknown	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Е	pipen Auto-Injector			S	Intramuscular	0.3 Mg	, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-May-2017	13514510	EXPEDITED (15-DAY)		I	HO, LT, OT	US-MYLANI 2017M1026				Unknown	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug Ineffective	E	pipen Auto-Injector			S	Intramuscular	0.3 Mg	, Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-May-2017	13515589	NON-EXPEDITED		I	T, OT	US-PFIZER 2017193984			45 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Device Failure; Device Use Issue; Drug Dose Omission; Needle Issu Product Quality Issue	e; C D A	pipen romoglicate Sodium iphenhydramine lcabo uloxetine Hydrochloride			S C C C	Intramuscular Oral	Unk, S Unk Q2-4h 40 Mg,	Qd		Pfi	zer
		albutamol			С		30 Mg, Unk, Q				
	Ip	ratropium rednisone			C C		Unk, Q				



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503E	B Facility Ag	<u>le</u>	<u>Sex</u>	Country
05-May-2017	13516826	NON-EXPEDITED		0	Γ	US-PFIZER 201719398		2 Y	/R	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Du</u>	ration	<u>Mfr</u>	
Drug Ineffective; Expire Product Administered					S	Intramuscular	0.15 Mg, Prn			Pfiz	
EDA Deseived Date	Epiper		1110-	Desct O	S	Mfn O and a	-1.# 5005	. Facilities Acc		Pfiz	
FDA Received Date		Case Type	Health		<u>utcomes</u>	Mfr Contr		S Facility Ag		<u>Sex</u>	Country
05-May-2017	13516941	NON-EXPEDITED		0	Γ	US-PFIZER 201719664				Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<b>Dosage Text</b>	<u>Du</u>	ration	<u>Mfr</u>	
Drug Ineffective	Epiper	1			S	Intramuscular	0.3 Mg, Once	e		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503E	B Facility Ag	<u>le</u>	<u>Sex</u>	Country
05-May-2017	13518881	EXPEDITED (15-DAY)		LT	, OT	US-MYLAN 2017M1026				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Du</u>	ration	<u>Mfr</u>	
Device Failure; Drug Ineffective	Epiper	Auto-Injector			S		0.3 Mg, Once	e		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol # 503E	Facility Ag	<u>le</u>	<u>Sex</u>	Country
05-May-2017	13519066	EXPEDITED (15-DAY)		0	Γ	US-MYLAN 2017M1026				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Du</u>	ration	Mfr	
Device Failure	Epiper	Auto-Injector			S	Intramuscular	0.3 Mg, Once	e		Myl	an
	Aspirin	/00002701/			С		81 Mg, Qd			Myl	an
	Nexiur	n /01479302/			С		20 Mg, Bid			Myl	an
	Norvas	SC .			С		5 Mg, Qd			Myl	an
	Synthr	oid			С		50 Mg, Qd			Myl	an
	Metopi	1-1			С		25 Mg, Qd			Myl	

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	Lorazepam			C 0.5 Mg, Prn						Му	<i>r</i> lan
	Sertralii	ne			С		50 Mg	, Qd		Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-May-2017	13519121	EXPEDITED (15-DAY)		Ľ	т, от	US-MYLANI 2017M1026	-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure; Drug Domission	Dose Epipen	Auto-Injector			S	Intramuscular	Unk U	nk, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-May-2017	13519214	EXPEDITED (15-DAY)		C	т	JP-PFIZER 2017147147			9 YR	Male	JPN
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	Mfr	
Anaphylactic Shock; Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	Epipen e	0.3mg			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-May-2017	13519225	NON-EXPEDITED		Н	O, LT, OT	US-PFIZER 2017199092			59 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	e Epipen				S	Intramuscular	0.3 Mg	g, Once		Pfi	zer
Quality 13306			Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date	Case #	Case Type	Hounn								
•	Case # 13519312	Case Type  NON-EXPEDITED	Health			US-PFIZER 2017199091	-		13 YR	Male	USA



#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

S Pfizer Accidental Exposure To Epipen Unk Product: Expired Product Administered: Injection Site Bruising; Injection Site Injury **Health Prof** Outcomes FDA Received Date Case # **Case Type** Mfr Control # 503B Facility Sex Country Age 08-May-2017 13522348 DIRECT OT 7 YR Male USA **Preferred Term Product OTC Dosage Text** Mfr Comp. Role Route Duration Accidental Exposure To Epi-Pen Jr. S Mylan Subcutaneous Product By Child; Injection С Claritin Site Pain; Injection Site C Flonase Swelling; Wrist Fracture FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Sex Country Age **US-MYLANLABS-**USA 13523043 **EXPEDITED (15-DAY)** LT, OT Unknown 08-May-2017 2017M1026667 **Duration Preferred Term Product OTC** Role **Dosage Text** Mfr Comp. Route Device Failure: Drug Epipen Auto-Injector S Mylan Intramuscular 0.3 Mg, Prn Ineffective FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Sex Age Country 08-May-2017 13524557 NON-EXPEDITED OT **US-PFIZER INC-**58 YR Female USA 2017200906 **Preferred Term OTC** Mfr **Product** Comp. Role Route **Dosage Text** Duration Drug Ineffective For Epipen S Pfizer Intramuscular 0.3 Mg, Once Unapproved Indication: S Prednisone 5 Mg, Prn Injection Site Pain: Musculoskeletal Stiffness FDA Received Date Case # **Health Prof Outcomes** Case Type Mfr Control # 503B Facility Age Sex Country NON-EXPEDITED **US-PFIZER INC-**13 YR USA 09-May-2017 13486623 HO, LT, OT Male 2017178577 **Preferred Term Product** Comp. OTC Role Route **Dosage Text** Duration Mfr



Drug Ineffective	Epipen				S	Intramuscular	0.3 Mg, Once		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2017	13497579	NON-EXPEDITED		(	TC	US-PFIZER IN 2017187723	IC-	30 YR	Male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mf</u> ı	<u>.</u>
Drug Ineffective	Epipen	0.3mg			S		0.3 Mg, Once		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2017	13527732	EXPEDITED (15-DAY)		(	TC	US-PFIZER IN 2017200798	IC-	365 DAY	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfı</u>	1
Cyanosis; Furuncle; Vomiting	Epipen				S		Unk		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2017	13528386	NON-EXPEDITED		l	₋T, OT	US-PFIZER IN 2017201091	IC-	15 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfı</u>	<u>.</u>
Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	Epipen				S		0.3 Mg, Once		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2017	13528387	NON-EXPEDITED		l	₋T, OT	US-PFIZER IN 2017200897	IC-	13 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	<u>.</u>
Device Failure; Device Use Issue; Drug Dose Omission; Product Qualssue	• •				S	Intramuscular	Unk Unk, Prn		Pf	izer

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2017	13528604	NON-EXPEDITED		Ľ	T, OT	US-PFIZEF 201720305				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Ineffective; Needle Iss Product Quality Issue		n 0.3mg			S	Intramuscular	0.3 Mg	g, Prn		Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-May-2017	13434465	EXPEDITED (15-DAY)		С	PΤ	JP-MYLAN 2017M102				Unknown	JPN
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Anaphylactic Shock; Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	Epipe	n			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-May-2017	13471564	NON-EXPEDITED		C	T	US-PFIZEF 201717250				Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	:
Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	Epipe	n			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-May-2017	13537128	EXPEDITED (15-DAY)		D	E	US-MYLAN 2017M102				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure; Drug D	ose Epipe	n Auto-Injector			S		Unk			Му	/lan
Omission	Epipe	n Auto-Injector			S					Му	/lan

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	Aspi	rin /00002701/			С	Oral	81 Mg, Qd			М	ylan
	Clar	tin /00917501/			С		Unk			M	ylan
	Core	eg .			С	Oral	6.25 Mg, Bio	t		M	ylan
	Lisin	opril			С	Oral	10 Mg, Qd			М	ylan
	Flon	ase			С		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503I	B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2017	13176901	NON-EXPEDITED				US-PFIZER 2017040017			16 YR	Male	USA
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text		<b>Duration</b>	<u>Mf</u>	<u>r</u>
Accidental Exposure Product; Chest Pain; Disturbance In Attenti Expired Product Administered; Feeling Jittery; Headache; Injection Site Bruising Injection Site Pain	ion;	en			S		Unk			Pi	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503I	B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2017	13497701	NON-EXPEDITED			LT	US-PFIZER 2017185370			68 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	<u>Role</u>	Route	Dosage Text		<b>Duration</b>	Mf	<u>r</u>
Device Failure; Drug I											
		en			S		Unk			Pi	fizer
Dmission; Product Qເ ssue; Wrong Technic	uality Epip que				S S		Unk 0.3 Mg, Unk				iizer iizer
Omission; Product Qu ssue; Wrong Technic n Product Usage Pro	uality Epip que ocess		<u>Health</u>	Prof		Mfr Contro	0.3 Mg, Unk	B Facility	Age		
Omission; Product Qu ssue; Wrong Technic n Product Usage Pro FDA Received Date	uality Epip que ocess	en	Health		S	Mfr Contro US-PFIZER 2017199089	0.3 Mg, Unk		<b>Age</b> 13 YR	Pi	iizer
Omission; Product Qualissue; Wrong Technic In Product Usage Pro FDA Received Date 12-May-2017  Preferred Term	uality Epip que coess  Case #  13519321	en <u>Case Type</u>	Health Comp.		S Outcomes LT, OT	US-PFIZER	0.3 Mg, Unk	B Facility		Sex	Country USA

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2017	13539286	NON-EXPEDITED			ОТ	US-PFIZER II 2017207830	NC-		39 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen				S	Intramuscular	0.3 Mg	g, Prn		Pfi	zer
	Prazosii	n			С		1 Mg,	Qd			
	Mirtazar	oine			С		15 Mg	ı, Qd			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2017	13541449 NON-EXPEDITED				US-PFIZER II 2017207829	NC-		54 YR	Unknown	USA	
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Dizziness; Expired Product Administered; Hyperhidrosis; Injectio Site Hypoaesthesia; Palpitations					S	Intramuscular	Unk U	Ink, Once		Pfi:	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-May-2017	13541984	EXPEDITED (15-DAY)			ОТ	US-MYLANLA 2017M102755				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen /	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2017	12680262	EXPEDITED (15-DAY)			ОТ	CA-PFIZER II 2016379502	NC-		80 YR	Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Confusional State;	Epipen	S		S		Unk. A	As Needed		Pfi	zer	

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Dizziness; Dysgeusia; Dyspnoea; Emotional Disorder; Epistaxis; Headache; Hypertension; Palpitations; Parosmia;

Tremor

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-May-2017	13473762	EXPEDITED (15-DAY)		Lī	Г, ОТ	US-MYLAN 2017M1023				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	Mfr	
Device Failure; Injection Site Laceration	on Epipen	Jr. Auto-Injector			S	Intramuscular	Unk L	Jnk, Once		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-May-2017	13406650	EXPEDITED (15-DAY)		Н	O, OT	JP-MYLANI 2017M1020	-			Unknown	JPN
Preferred Term	Produc	<u>.t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Use Issue; Nee ssue; Therapeutic Response Decreased	edle Epipen				S		Unk			Му	⁄lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-May-2017	13515545	NON-EXPEDITED		DI	E	US-PFIZER 201718989				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Jse Issue; Drug neffective; Product Quality Issue	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-May-2017	13548878	NON-EXPEDITED				US-PFIZER 201721257	-		3 YR	Male	USA
Preferred Term	Produc	+	Comp.	отс	Role	Route	Dosage	o Toyt	Duration	Mfr	



#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

S Pfizer Accidental Exposure To Epipen Unk Product By Child; Injection Site Coldness FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Age **Sex Country US-PFIZER INC-**USA 16-May-2017 13549931 NON-EXPEDITED DE 64 YR Male 2017210377 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text Duration** Mfr S Device Failure: Device **Epipen** Pfizer Unk Use Issue: Drug Dose S Pfizer **Epipen** Omission; Needle Issue; Aspirin /00002701/ С 81 Mg, Qd Oral Product Quality Issue Claritin /00917501/ С Unk Coreg C Oral 6.25 Mg, Bid Lisinopril С Oral 10 Mg, Qd Flonase С Unk FDA Received Date Case # **Health Prof Outcomes** 503B Facility Country Case Type Mfr Control # Age Sex 13551805 **EXPEDITED (15-DAY)** LT, OT **US-PFIZER INC-**2 YR Male USA 16-May-2017 2017180734 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text** Duration Mfr Device Failure: Device Epipen Jr S Pfizer Unk Unk. Once Intramuscular Use Issue: Injection Site Laceration; Needle Issue; Product Quality Issue; Underdose **Health Prof Outcomes** FDA Received Date Case # **Case Type** Mfr Control # 503B Facility Sex Age Country **GB-PFIZER INC-EXPEDITED (15-DAY)** OT **GBR** 17-May-2017 13406968 Unknown 2017149441 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text Duration** Mfr Device Failure: Device S Pfizer Epipen Unk Use Issue; Panic Attack; Post-Traumatic Stress Disorder: Product Quality



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Issue											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2017	13434141	EXPEDITED (15-DAY)		0.	Γ	IE-MYLANLA 2017M10227				Unknown	IRL
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage <sup>-</sup>	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure		en (Epinephrine) Auto or 0.3 Mg			S	Intramuscular	Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2017	13434454	EXPEDITED (15-DAY)		Н	O, LT	IE-MYLANLA 2017M10219	995			Unknown	IRL
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage <sup>-</sup>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe Inject			S	Intramuscular	Unk			Myl	an	
	Symb			С	Respiratory (inhalation)	Unk Unl	k, Prn		Myl	an	
	Vento	oline /00139501/			С	Respiratory (inhalation)	Unk Unl	k, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2017	13561398	EXPEDITED (15-DAY)		0.	Γ	US-MYLANL 2017M10287				Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage <sup>-</sup>	<u>Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2017	13561539	EXPEDITED (15-DAY)	,		US-MYLANL 2017M10290	-			Unknown	USA	
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage <sup>-</sup>	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug Domission	evice Failure; Drug Dose Epipen Auto-Injector mission				S	Intramuscular	0.3 Mg,	Once		Myl	an



FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-May-2017	13561842	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2017M1029				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>	Mfr	
Drug Ineffective	Epiper	n Auto-Injector			S	Intramuscular	0.3 M	g, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561873	EXPEDITED (15-DAY)			ОТ	NZ-MYLANI 2017M1029				Unknown	NZL
Preferred Term	Produ	ıct	Comp.	OTO	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Use Issue	Jse Issue Epipen Auto-Injector				S	Intramuscular	0.3 M	g, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2017	13564778	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1028				Unknown	USA
Preferred Term	Produ	ıct	Comp.	OTO	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	Mfr	
Depressed Level Of	Epiper	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Myl	an
Consciousness; Gait Disturbance; Loss Of	Spryce	el /05677301/			С		100 M	lg, Qd		Myl	an
Consciousness; Senso	ory Alpraz	olam			С		2 Mg,	Tid		Myl	an
Loss	Gabap	pentin			С		300 M	lg, Tid		Myl	an
	Amitri	otyline			С		75 Mg	յ, Qd		Myl	an
	Trama	dol			С		50 Mg	g, Bid		Myl	an
	Paxil /	00830802/			С		20 Mg	յ, Qd		Myl	an
	Cyano	cobalamin			С		1000	Mg, Monthly		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-May-2017	13564850	EXPEDITED (15-DAY)			LT	NL-MYLANI 2017M1030				Unknown	NLD
Preferred Term	Produ	<u>ıct</u>	Comp.	отс	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	

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Device Failure; Needle ssue	Epipen				S		0.3 Mg	g, Unk		Му	lan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
19-May-2017	13565183	EXPEDITED (15-DAY)		LT	, OT	US-MYLANL 2017M10290				Unknown	USA	
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>		
Device Failure; Drug D Dmission	ose Epipen	Auto-Injector			S		Unk			Му	lan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
19-May-2017	13565187	EXPEDITED (15-DAY)		LT	-	NL-MYLANL 2017M10304				Unknown	NLD	
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>		
Device Failure; Needle ssue	vice Failure; Needle Epipen Auto-Injector		S			Unk			Mylan			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
22-May-2017	13567403	NON-EXPEDITED		LT	, OT	US-PFIZER 2017222170	INC-		71 YR	Female	USA	
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr		
Orug Ineffective	Epipen				S	Intramuscular	0.3 Mg	g, Once		Pfiz	zer	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
22-May-2017	13568649	EXPEDITED (15-DAY)		0	Γ	US-MYLANL 2017M10294				Unknown	USA	
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr		
Device Failure; Intentio Product Misuse	nal Epipen	Auto-Injector			S		Unk			Му	lan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
22-May-2017	13569153	NON-EXPEDITED		0	Γ	US-PFIZER 2017222171	INC-		16 YR	Male	USA	



Preferred Term		<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	I	Epipen Jr			S	Intramuscular	0.3 Mg, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2017	1356949	91 EXPEDITED (15-DAY)	)		ОТ	US-PFIZER 2017224417		37 YR	Female	USA
Preferred Term	]	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Depressed Level Of	ļ	Epipen 0.3mg			S	Intramuscular	0.3 Mg, Prn		Pfiz	zer
Consciousness; Gait Disturbance; Loss Of	;	Sprycel /05677301/			С		100 Mg, Qd			
Consciousness; Senso	ory /	Alprazolam			С		2 Mg, Tid			
Loss	(	Gabapentin			С		300 Mg, Tid			
	,	Amitriptyline			С		75 Mg, Qd			
	-	Tramadol			С		50 Mg, Bid			
	Paxil /00830802/				С		20 Mg, Qd			
	(	Cyanocobalamin			С		1000 Mg, Monthly			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-May-2017	1356960	00 EXPEDITED (15-DAY	)		HO, LT, OT	US-MYLANI 2017M1029	_		Unknown	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose l	Epipen Auto-Injector			S	Intramuscular	Unk Unk, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-May-2017	1357805	54 EXPEDITED (15-DAY)	)		LT	NZ-MYLANI 2017M1030			Unknown	NZL
Preferred Term	1	<u>Product</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure; Device Use Issue; Drug Dose Omission		Epipen Junior			S	Intramuscular	0.15 Mg, Once		Му	lan

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
25-May-2017	13579450	EXPEDITED (15-DAY)		(	TC	US-MYLAN 2017M1029				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	0.3 M	g, Once		Му	an
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Conti	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2017	13580865	EXPEDITED (15-DAY)		(	TC	JP-MYLAN 2017M102				Unknown	JPN
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Device Failure; Device Use Issue; Drug Dose Omission; Needle Issu Product Quality Issue					S		0.3 M	g, Once		Му	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Conti	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-May-2017	13596660	DIRECT		I	HO, OT				16 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Quality Issue; Product Issue		2pak Auto Injectors.3mg ryl			S C	Intramuscular	Quan	tity:1 Injection(S);		Му	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2017	13586556	EXPEDITED (15-DAY)		(	TC	US-MYLAN 2017M103				Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>otc</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipen	Auto-Injector			S		Unk			Му	an
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-May-2017	13586872	EXPEDITED (15-DAY)		(	TC	US-MYLAN 2017M103				Unknown	USA



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Preferred Term	Prod	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-May-2017	13591316	NON-EXPEDITED		C	T	US-PFIZEF 201723333		52 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipe	en			S	Intramuscular	0.3 Mg, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2017	13592367 NON-EXPEDITED  Product					US-PFIZEF 201723561		58 YR	Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Urticaria	Epipen 0.3mg				S	Intramuscular	0.3 Mg, Once		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jun-2017	13602039	NON-EXPEDITED		C	T	US-ARBOF PHARMAC LLC-US- 2016ARB0	EUTICALS,		Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>Mfr</u>	
Anxiety; Depression;	Gaba	pentin Enacarbil			S	Oral	300 Mg, Qd, 300 Mg,	Daily	Arb	oor
Headache; Hypersensitivity; Inson Off Label Use; Panic Attack; Suicidal Ideatic	adache; bersensitivity; Insomnia; Label Use; Panic  Hydrochlorothiazide Benadryl /00000402/				C C S		As Needed			
Urinary Incontinence	rinary Incontinence							_		
FDA Received Date	Case #	Case Type	<u>Health</u>		utcomes	Mfr Contr		<u>/ Age</u>	<u>Sex</u>	Country
02-Jun-2017	13568634	EXPEDITED (15-DAY)		F	0	US-PFIZEF 201721754			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>Mfr</u>	



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Contraindicated Produc Administered; Throat Tightness	t Epipen				S		Unk			Pf	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2017	13605945	NON-EXPEDITED		(	TC	US-PFIZER 201723584	-		19 YR	Female	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfı</u>	•
Abdominal Discomfort; Chest Pain; Drug Ineffective	Epipen J Benadryl				S C	Intramuscular	0.3 Mg Unk	յ, Prn		Pf	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2017	13609317	EXPEDITED (15-DAY)		ł	НО	JP-MYLANI 2017M1033	-			Unknown	JPN
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfı</u>	
Blood Pressure Increas					S		Unk			My	/lan
Palpitations; Product Us In Unapproved Indication					S		Unk			My	/lan
m onapproved maleatio	Epipen				S		Unk			My	/lan
	Epipen				S		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jun-2017	13609457	EXPEDITED (15-DAY)		I	HO, LT, OT	US-MYLAN 2017M1032	-			Unknown	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mf</u> ı	•
Drug Ineffective; Expire	d Epipen A	uto-Injector			S	Intramuscular	0.3 Mg	ı, Once		My	/lan
Product Administered	Zoloft				С		Unk	,		My	/lan
	Estrogen	ı			С		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof (	<u> Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2017	13615350	NON-EXPEDITED		I	_T, OT	US-PFIZER 201724524			46 YR	Female	USA



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Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>M1</u>	<u>ir</u>
Drug Effect Decreased; Expired Product Administered; Headach					S	Intramuscular	0.3 Mg	, Prn		Р	fizer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2017	13615672	NON-EXPEDITED			HO, LT, OT	US-PFIZEF 201724312			35 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Drug Ineffective; Expire Product Administered	ed Epipen Zoloft Estroge				S C C	Intramuscular	0.3 Mg Unk Unk	, Once		Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
7-Jun-2017 13586156 NON-EXPEDITED		NON-EXPEDITED				US-PFIZEF 201723335	-		3 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Accidental Exposure To Epipen ( Product By Child; Heart Rate Increased; Injection Site Haemorrhage		0.3mg			S		0.3 Mg	, Once		Р	fizer
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jun-2017	13602397	EXPEDITED (15-DAY)			НО	JP-PFIZER 201723245			64 YR	Female	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Blood Pressure Increas		0.3mg			S		Unk			Р	fizer
Palpitations; Product Us In Unapproved Indication		0.3mg			S		Unk			Р	fizer
Capprovod maloutic	Epipen (	0.3mg			S		Unk			Р	fizer
	Epipen (	0.3mg			S		Unk			Р	fizer



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

EDA Bassivad Data	Case #	Casa Tura	Llaalth	Drof	Outcomes	Mfr Contro	-1.4	FOOD Facility	Λαο	Cov	Country
	Case #	Case Type	<u>meaith</u>		Outcomes	Mfr Contro		503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2017	13636209	EXPEDITED (15-DAY)			LT, OT	US-MYLANI 2017M1032	_			Unknown	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Orug Ineffective	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jun-2017	13636273	EXPEDITED (15-DAY)		I	LT, OT	US-MYLANI 2017M1033	_			Unknown	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2017	13616309	EXPEDITED (15-DAY)		I	LT	BE-MYLANL 2017M1033				Unknown	BEL
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	1 Df, T	Гotal		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2017	13642699	EXPEDITED (15-DAY)		I	LT, OT	US-MYLANI 2017M1034				Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure; Drug D Omission; Injection Sit Laceration; Needle Iss	е	n Jr. Auto-Injector			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jun-2017	13643209	EXPEDITED (15-DAY)		•	ОТ	US-MYLANI 2017M1034				Unknown	USA
Preferred Term	<u>Produ</u>		Comp.	OTC	Role	Route	Dosage		<u>Duration</u>	<u>Mfr</u>	



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							•				
Device Failure	Epipen	Auto-Injector	S Unk						My	ylan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13644245	NON-EXPEDITED		L	T, OT	US-PFIZER 201725528			14 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective	Epipen				S	Intramuscular	0.3 M	g, Prn		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jun-2017	13650143	NON-EXPEDITED		F	IO, LT, OT	US-PFIZER 201725765	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	1
Drug Ineffective	Epipen		S Unk			Pf	izer				
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jun-2017	13650604	NON-EXPEDITED		C	T	US-PFIZER 2017255399			10 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>.</u>
Device Failure; Device Use Issue; Injection Si Erythema; Product Qu Issue	te				S	Intramuscular	0.3 M	g, Once		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jun-2017	13650694	EXPEDITED (15-DAY)		F	IO, OT	JP-MYLANI 2017M1035				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mf	<u>.</u>
Hospitalisation	Epipen		S			Unk			My	ylan	
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2017	13402572	EXPEDITED (15-DAY)		L	T, OT	US-MYLAN 2017M1020				Unknown	USA



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Preferred Term	<u>Prod</u> ı	uct	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Device Failure; Dyspno Injection Site Bruising; Injection Site Haemorrhage	• •	n Auto-Injector n Auto-Injector			S S		Unk Unk			Myl Myl	
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2017	13418864	EXPEDITED (15-DAY)		Н	O, OT	US-MYLANLABS- 2017M1021195			Unknown	USA	
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route Dosage Text		<b>Duration</b>	Mfr		
levice Failure; Epipen Auto-Injector lypertension; Migraine				S	Intramuscular	0.3 Mg,	Once		My	an	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Jun-2017	13654761	EXPEDITED (15-DAY)		Н	0	US-MYLANI 2017M1034				Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure	Epipe	n Auto-Injector			S					My	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2017	13444812	EXPEDITED (15-DAY)		Н	O, OT	US-PFIZER 2017160759			31 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	Mfr	
Arrhythmia; Blood	Epipe	n			S	0.3 Mg, Unk [Upper Thig			nigh] Pfizer		
Pressure Increased; Product Use Issue;	Lyrica	ı			С		225 Mg, 2x/Day				
Regurgitation;	Dimet	арр			С		Unk				
Tachycardia	Omep	orazole			С		Unk				
	Nexiu	m			С		Unk				
	Depo	Provera			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2017	13659476	EXPEDITED (15-DAY)		Н	O, OT	US-MYLANLABS- 2017M1034865			Unknown	USA	

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Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D Omission; Keloid Scar		Auto-Injector			S	Intramuscular	0.3 Mg, Once		My	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2017	13659486	EXPEDITED (15-DAY)			LT, OT	US-MYLANL 2017M10342			Unknown	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Prn		My	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2017	13661187	NON-EXPEDITED				US-PFIZER 2017264557	_	10 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T	o Epipen				C				Pfiz	
Product By Child; Injur Associated With Devic Needle Issue	У				S	Intramuscular	0.15 Mg, Prn		FIIZ	er
Product By Child; Injur Associated With Devic	y e;	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Intramuscular  Mfr Contro		<u>Age</u>	Sex	<u>Country</u>
Product By Child; Injur Associated With Devic Needle Issue	y e;		<u>Health</u>				503B Facility	<u>Age</u>		
Product By Child; Injur Associated With Devic Needle Issue FDA Received Date	y e; <u>Case #</u>	Case Type NON-EXPEDITED	Health Comp.		<u>Outcomes</u> HO	Mfr Contro	503B Facility	Age Duration	<u>Sex</u>	Country
Product By Child; Injur Associated With Devic Needle Issue FDA Received Date 16-Jun-2017	y e;  Case #  13661193  Produ	Case Type  NON-EXPEDITED  ct			<u>Outcomes</u> HO	Mfr Contro US-PFIZER 2017264326	503B Facility INC-	-	<u>Sex</u> Female	Country USA
Product By Child; Injur Associated With Devic Needle Issue  FDA Received Date  16-Jun-2017  Preferred Term  Device Failure; Device Use Issue; Drug Dose Omission; Product Qua	Case # 13661193  Produ Epiper	Case Type  NON-EXPEDITED  ct	Comp.	<u>010</u>	Outcomes HO	Mfr Contro US-PFIZER 2017264326	Dosage Text Unk	-	Sex Female Mfr	Country USA
Product By Child; Injur Associated With Devic Needle Issue  FDA Received Date  16-Jun-2017  Preferred Term  Device Failure; Device Use Issue; Drug Dose Omission; Product Qual Issue	Case # 13661193  Produ Epiper	Case Type  NON-EXPEDITED  ct	Comp.	OTO Prof	Outcomes HO Role S	Mfr Contro US-PFIZER 2017264326 Route	Dosage Text Unk  503B Facility Unk  503B Facility Unk	<u>Duration</u>	Sex Female Mfr Pfiz	Country USA zer
Product By Child; Injur Associated With Devic Needle Issue  FDA Received Date  16-Jun-2017  Preferred Term  Device Failure; Device Use Issue; Drug Dose Omission; Product Qual Issue  FDA Received Date	Case #  13661193  Produ Epiper	Case Type NON-EXPEDITED  Ct Jr  Case Type NON-EXPEDITED	Comp.	OTO Prof	Outcomes HO Role S Outcomes OT	Mfr Contro US-PFIZER 2017264326 Route Mfr Contro US-PFIZER	Dosage Text Unk  503B Facility Unk  503B Facility Unk	<u>Duration</u>	Sex Female  Mfr Pfiz	Country USA rer

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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Jun-2017	13661643	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2017M1034	_			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure		Auto-Injector Auto-Injector			S S	Intramuscular	0.3 Mg	g, Prn		My My	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jun-2017	13663509	NON-EXPEDITED				US-PFIZER 201726455				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product; Anxiety; Expir Product Administered; Palpitations		0.3mg			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jun-2017	13675439	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1035	_			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Injectio	n Epipen i	Auto-Injector			S		Unk			Му	lan
Site Discolouration; Injection Site Swelling	Loratadi	ine			С		Unk			Му	lan
injection one owening	Multivita	min /00097801/			С		Unk			Му	lan
	Norvaso Atenolol Estrace				C C C		Unk			My My My	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2017	13434334	NON-EXPEDITED			но, от	US-PFIZER 201715337			49 YR	Female	USA
				отс	Role		Dosage				

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S Pfizer Device Failure: Device Epipen 0.3mg Intramuscular 0.3 Mg, Once Use Issue; Hypertension; Migraine; Product Quality Issue FDA Received Date Case # Mfr Control # **Case Type Health Prof** Outcomes 503B Facility Sex Country <u>Age</u> **US-PFIZER INC-**22-Jun-2017 13679764 **EXPEDITED (15-DAY)** HO, LT, OT Female USA 2017268344 **Preferred Term Product** Comp. **OTC** Role **Route Dosage Text Duration** Mfr Device Failure: Device Epipen S Pfizer Unk Use Issue: Drug Dose Omission: Product Quality Issue: Renal Failure FDA Received Date Case # **Case Type Health Prof** Outcomes Mfr Control # **503B Facility** Age Sex Country DS USA 22-Jun-2017 13681931 DIRECT Υ 49 YR Female **Preferred Term Product** Comp. **OTC Role Route Dosage Text Duration** Mfr S Accidental Overdose: Simvastatin 20mg Tablet S Brain Injury Alprazolam 0.25mg S Olanzapine 15mg S Aripiprazole 10 Mg S Escitalopram 20mg S Lantus S Metformin S Meloxicam 15mg S Omeprazole 20mg Toviaz Er S S Divalproex Sod S Propranolol 40mg Tab Her S Ibuprofen S Ventolin Hfa Epipen S **503B Facility** FDA Received Date Case # **Health Prof Outcomes** Mfr Control # Case Type <u>Age</u> Sex Country JP-PFIZER INC-23-Jun-2017 13438816 **EXPEDITED (15-DAY)** LT, OT 18 YR JPN Male 2017111622



#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	[
Dyspnoea	Epipen	0.3mg			S		Unk		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2017	13648470	NON-EXPEDITED		Ľ	T, OT	US-PFIZER 2017255312		36 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<b>Duration</b>	Mf	1
Device Failure; Device Use Issue; Drug Dose Omission; Product Qu Issue					S	Intramuscular	0.3 Mg, Once		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2017	13664711	EXPEDITED (15-DAY)		C	Т	CH-MYLANI 2017M10362			Unknown	CHE
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	Mf	<u>r</u>
Device Failure; Expire Product Administered	d Epipen				S		Unk		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jun-2017	13689341	DIRECT		R	1			7 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>.</u>
Injection Site Reaction Laceration; Needle Iss		ı Jr			S C					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2017	13518883	EXPEDITED (15-DAY)		Ľ	T, OT	US-MYLANI 2017M1026			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mf	<u>.</u>
Device Failure Epipen Auto-Injector				0				N 43	don	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	Unk Unk, Prn		IVI	ylan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jun-2017	13586194	EXPEDITED (15-DAY)		01	Г	JP-MYLANL 2017M1031	-			Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Device Failure; Device Use Issue; Needle Issu Product Quality Issue					S S S	Intramuscular Intramuscular	Unk Unk Unk			Myl Myl Myl	lan
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jun-2017	13330491	EXPEDITED (15-DAY)		01	Г	CH-MYLANI 2017M1015	-			Unknown	CHE
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Device Failure; Wrong Technique In Device Usage Process	Epipen .	Jr			S					My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jun-2017	13693792	NON-EXPEDITED		НС	), LT, OT	US-PFIZER 2017277345			61 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Device Failure; Device Use Issue; Drug Ineffective; Needle Issu					S		0.3 M	g, Unk		Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	ıtcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2017	13675295	NON-EXPEDITED		НС	), LT, OT	US-PFIZER 2017264459				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Device Failure; Device Use Issue; Drug Effect Incomplete; Product Quality Issue					S S		Unk			Pfiz Pfiz	



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13655721	NON-EXPEDITED		0	Т	US-PFIZER 201726058				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epiper	1			S		Unk			Pfi	izer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2017	13656318	NON-EXPEDITED		Ľ	Г, ОТ	US-PFIZER 201726158	-		2 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	<u>r</u>
Device Failure; Device Use Issue; Drug Dose Omission; Injection Sit Laceration; Needle Iss Product Quality Issue	e	n Jr			S		Unk			Pfi	izer
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jun-2017	13703234	EXPEDITED (15-DAY)		Ľ	Г, ОТ	US-MYLAN 2017M1037				Unknown	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	<u>.</u>
Abdominal Discomfort		n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		My	ylan
Device Failure; Expired Product Administered	d Lisino <sub>l</sub>	oril			С	Oral	20 Mg	ı, Qam			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2017	13427904	NON-EXPEDITED		L	Г, ОТ	US-PFIZER 201714906			15 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	Mfr	1
Device Failure; Device		١			S		Unk			Pfi	izer
Use Issue; Dyspnoea; Expired Product	Epiper	า			S		Unk			Pfi	izer
Administered; Injection Site Bruising; Injection Haemorrhage; Production	Site	lryl			С		Unk				

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Quality Issue											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2017	13674760	NON-EXPEDITED		0	Т	US-PFIZER 201726432	-			Unknown	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epiper	1			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2017	13675294	NON-EXPEDITED		Н	0	US-PFIZER 201726446	-			Male	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Dose Omission; Product Qualssue		1			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2017	13685372	EXPEDITED (15-DAY)		DI	E, OT	US-PFIZER 201727504				Female	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Death	Epiper	1			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2017	13707431	NON-EXPEDITED		Lī	T, OT	US-PFIZER 2017285003			49 YR	Female	USA
Preferred Term	Produ	ct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort		n 0.3mg			S	Intramuscular	0.3 Mg	, Prn		Pfiz	zer
Device Failure; Device Use Issue; Expired Product Administered; Product Quality Issue	LISITIO	oril			С	Oral	20 Mg,	Qam			



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2017	13708467	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1038	_			Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosa	age Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Expired	l Epipei	n Auto-Injector			S		Unk	(		Му	lan
Product Administered	Wellbu	utrin			С		150	Mg, Qd		Му	lan
	Vyvan	se			С		20 [	Mg, Qd		Му	lan
	Ephed	Irine			С		Unk	k, Prn		Му	lan
	Benac	Iryl /0000402/			С		Unk	k, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2017	13361266	EXPEDITED (15-DAY)			ОТ	JP-MYLAN 2017M1018	_			Unknown	JPN
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosa	age Text	<b>Duration</b>	Mfr	
Device Failure; Device Use Issue; Needle Issu Product Quality Issue	Epipei e;	า			S		0.3	Mg, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jul-2017	13711409	EXPEDITED (15-DAY)			ОТ	FR-MYLAN 2017M1039				Unknown	FRA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<b>Duration</b>	<u>Mfr</u>	
Hyperhidrosis; Hypertension; Malaise; Pallor; Tachycardia; Tremor	• •	n Auto-Injector			S	Intramuscular		ly Dose: 0.3 Mg gram(S) Every Total		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jul-2017	13719362	EXPEDITED (15-DAY)			ОТ	FR-PFIZER 201729249			27 YR	Male	FRA
Preferred Term	Produ	uot.	Comp.	ОТС	Role	Route	Deer	age Text	Duration	Mfr	



Accidental Exposure To Product; Hyperhidrosis; Hypertension; Malaise; Pallor: Tachycardia: Epipen 0.3mg

S Intramuscular

Daily Dose: 0.3 Mg Millgram(S) Every Total Pfizer

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2017	13722130	NON-EXPEDITED		0	Γ	US-PFIZER 201728532	-		59 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen		S Intramuscular 0.3 Mg, Once			Pfiz	er				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2017	13722159	NON-EXPEDITED		0	Γ	US-PFIZER 201728526	-		16 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen		S Unk			Pfiz	er				
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jul-2017	13726506	EXPEDITED (15-DAY)		0	Γ	AU-MYLAN 2017M1039	-			Unknown	AUS
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen				S					Му	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jul-2017	13733686	EXPEDITED (15-DAY)		Н	O, LT, OT	US-MYLAN 2017M1039	-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen .	Auto-Injector		S Unk			Му	an			
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2017	13423504	NON-EXPEDITED		0	Г	US-PFIZER 201715109	-		63 YR	Female	USA

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Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Palpitations	Epipen 3				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2017	13591410	NON-EXPEDITED		L	T, OT	US-PFIZE 201720109	-		49 YR	Female	USA
Preferred Term	Product	<u> </u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Device Failure; Device	Epipen				S	Intramuscular	0.3 M	g, As Needed		Pfi	zer
Use Issue; Drug Dose Omission; Drug	Epipen				S	Intramuscular	0.3 M	g, Unk		Pfi	zer
Ineffective; Product Quality Issue	Asa				С	Oral	4 Df,	Qd			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2017	13745614	EXPEDITED (15-DAY)		H	IO, OT	US-PFIZE 20172977			5 YR Male USA		
Preferred Term	Product	<u>I</u>	Comp.	OTC	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Pancreatitis Acute;	Epipen .	Ir			S	Intramuscular	0.15	Mg, Once		Pfi	zer
Rotavirus Infection	Zofran /0	00955301/			С		Unk				
	Solumed	drol			С		Unk				
	Benadry	I			С		Unk				
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2017	13746516	EXPEDITED (15-DAY)		C	T	AU-MYLAI 2017M104				Unknown	AUS
Preferred Term	Product	1	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Device Malfunction	Epipen A	Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2017	13746518	EXPEDITED (15-DAY)		C	DT	AU-MYLAN 2017M104	-			Unknown	AUS



							•				
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>Mf</u>	
Device Malfunction	Epipen	Auto-Injector			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2017	13746519	EXPEDITED (15-DAY)		0	Т	AU-MYLAN 2017M104				Unknown	AUS
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mf</u>	
Device Malfunction	Epipen	Auto-Injector			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2017	13747337	EXPEDITED (15-DAY)		0	Т	US-MYLAN 2017M104	_			Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp. OTC Role Route Dosage Text					Text	<b>Duration</b>	<u>Mf</u> ı	
Expired Product Administered; Injection Site Pain; Pain	ministered; Injection				S	Intramuscular	0.3 Mg	, Prn		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2017	13749064	EXPEDITED (15-DAY)		0	Т	US-PFIZEI 201730013			33 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mf</u>	!
Expired Product Administered; Injection Site Pain; Pain	Epipen 1				S	Intramuscular	0.3 Mg	, Prn		Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2017	13735359	NON-EXPEDITED				US-PFIZEI 201728792				Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>Mf</u>	
Accidental Exposure T Product; Headache; Lethargy; Nausea; Pro Quality Issue; Product	duct				S		0.3 Mg,	, Unk		Pf	izer

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Issue; Vomiting											
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2017	13758946	EXPEDITED (15-DAY)		Н	0	JP-MYLANI 2017M1043				Unknown	JPN
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Hospitalisation	Epipei	า			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2017	13760729	EXPEDITED (15-DAY)		0	Т	JP-MYLANI 2017M1041				Unknown	JPN
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Drug Effect Incomplete	e Epipei	า			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jul-2017	13761501	EXPEDITED (15-DAY)		0	Т	AU-MYLAN 2017M1042				Unknown	AUS
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Breakage; Dev Issue; Device Leakage		n Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jul-2017	13770413	EXPEDITED (15-DAY)		L	Г, ОТ	US-MYLAN 2017M1041				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	lan
	Epipei	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2017	13507778	NON-EXPEDITED				US-PFIZER 2017191898	-		15 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	

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Injection Site Pain	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof Ou	ıtcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jul-2017	13775371	NON-EXPEDITED				US-MYLAN 2017M1026	-		58 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication Injection Site Moveme Impairment; Injection S Pain	n; Prednis nt	Auto-Injector sone			S S	Intramuscular	0.3 M 5 Mg,	g, Once Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>ıtcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2017	13779878	EXPEDITED (15-DAY)		ОТ	Г	GB-MYLAN 2017M1043	-		Unknown ITA  Duration Mfr		
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>		
Drug Ineffective	Epipen				S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Jul-2017	13779974	EXPEDITED (15-DAY)		01	Г	US-MYLAN 2017M1042	-			Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	Unk L	Jnk, Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof Ou	ıtcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2017	13782048	NON-EXPEDITED		01	Г	US-PFIZER 2017317564			48 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Effect Incomplete; Product Quality Issue; Tremor					S	Intramuscular	0.3 M	g, Single (Once)		Pfi	zer



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2017	13782334	DIRECT	Υ							Unknown	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>le Text</u>	<u>Duration</u>	<u>Mf</u>	ŗ
Accidental Exposure T Product; Product Labe Issue		n Epinephrine			S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jul-2017	13782761	EXPEDITED (15-DAY)		(	TC	US-MYLAN 2017M1042	_			Unknown	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	<u>r</u>
Device Failure; Drug Ineffective; Tremor	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	lg, Once		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jul-2017	13789954	NON-EXPEDITED		(	TC	US-PFIZER 2017317632			74 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mf	<u>r</u>
Drug Ineffective	Epipe Chlora	n Jr amphenicol			S C	Intramuscular	0.3 M Unk	lg, Prn		Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Jul-2017	13792953	DIRECT		(	TC				8 YR	Male	USA
Preferred Term	Produ	uct	Comp.	OTC	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mf	r
Device Malfunction; Medical Device Site Ponting Needle Issue; Needle Issue	Epipe ain;	n Jr.			S					М	ylan



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FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2017	13773200	EXPEDITED (15-DAY)		0	Г	JP-PFIZER 2017298652			40 YR	Female	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Blood Pressur Increased; Heart Rate Increased; Palpitations	re				S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jul-2017	13800805	EXPEDITED (15-DAY)		0	Г	AU-MYLANI 2017M1043				Unknown	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Device Leakage; Devic Malfunction	ce Epipen				S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2017	13661681	EXPEDITED (15-DAY)		Lī	г, от	US-MYLANI 2017M1034				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen .	Auto-Injector			S		0.3 Mg	g, Once		Му	lan
	Epipen .	Auto-Injector			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2017	13803068	EXPEDITED (15-DAY)		0	Г	US-MYLANI 2017M1043	-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jul-2017	13803340	NON-EXPEDITED		0	Γ	US-PFIZER 2017319114				Unknown	USA



Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u> 50</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jul-2017	13711225	EXPEDITED (15-DAY)		D	E	GB-MYLANI 2017M1039				Unknown	GBR
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen	Auto-Injector			S	Intramuscular	1 Df, Tota	al		Myla	an
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>50 #</u>	03B Facility	Age	<u>Sex</u>	Country
31-Jul-2017	13586555	EXPEDITED (15-DAY)		Ľ	T, OT	US-MYLANI 2017M10300				Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Contusion; Device Fail	ure Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, P	rn		Myla	an
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u> 50</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2017	13817603	NON-EXPEDITED				US-PFIZER 2017328254			51 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Scar	Epipen	1			S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>50 #</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jul-2017	13818646	EXPEDITED (15-DAY)		C	·Τ	GB-MYLANI 2017M1045				Unknown	GBR
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Device Failure		(Epinephrine) Auto r 0.3 Mg			S		Unk			Myla	an

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Aug-2017	13821886	NON-EXPEDITED		l	_T, OT	US-PFIZER 2017330125			74 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Ineffective	Epipen				S	Intramuscular	0.3 M	lg, Prn		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2017	13824598	DIRECT		l	_T				41 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Device Malfunction; Product Quality Issue	Epipen				S					Му	rlan .
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2017	13825964	EXPEDITED (15-DAY)		l	₋T, OT	US-MYLAN 2017M1045				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipen /	Auto-Injector			S	Intramuscular	0.3 M	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2017	13827461	EXPEDITED (15-DAY)		(	OT	FR-MYLANI 2017M1046				Unknown	FRA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Exposure Du Pregnancy; Injection S Discolouration; Wrong Technique In Product Usage Process	ring Site				S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Aug-2017	13733674	EXPEDITED (15-DAY)		(	ОТ	GB-MYLAN 2017M1041				Unknown	GBR



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<u>Preferred Term</u>	<u>Produc</u>	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug Do Omission; Needle Issue		Jr			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Aug-2017	13835216	EXPEDITED (15-DAY)		0	Γ	FR-PFIZER 2017337114	-			Female	FRA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Accidental Exposure To Product; Injection Site Discolouration; Wrong Technique In Product Usage Process	o Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Aug-2017	13836263	EXPEDITED (15-DAY)		0	Г	CA-PFIZER 2017338095	-		30 YR	Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mfr</u>	
Abortion Spontaneous	Epipen .	Jr			S	Intramuscular	0.3 Mg	, Unk		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2017	12841498	EXPEDITED (15-DAY)		0	Γ	US-MYLANI 2016M1043	-			Unknown	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Device Failure	Epipen				S	Intramuscular				Myl	an
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2017	13711418	EXPEDITED (15-DAY)		0	Г	GB-MYLANI 2017M1039				Unknown	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mfr	
Drug Effect Incomplete Epipen											



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2017	13822132	EXPEDITED (15-DAY)		D	E, LT, OT	US-PFIZER 2017320598	INC-	7 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>I</u>	<u>Mfr</u>
Asthma; Brain Death; Cardiac Arrest; Drug Ineffective; Hypersensitivity; Hypo	Epipen Epipen oxia				S S		Two Epipens (2 Df)			Pfizer Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2017	13837911	EXPEDITED (15-DAY)		L	T, OT	US-MYLANL 2017M10460	=		Unknow	n USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>I</u>	<u>Mfr</u>
Drug Effect Decreased Expired Product Administered	d; Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Prn			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2017	13841503	NON-EXPEDITED		L	T, OT	US-PFIZER 2017338093			Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	1	<u>Mfr</u>
Drug Effect Decreased Expired Product Administered	d; Epipen				S	Intramuscular	0.3 Mg, Prn			Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Aug-2017	13841509	NON-EXPEDITED		Н	O, OT	US-PFIZER 2017337809	INC-	11 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Drug Ineffective	Epipen	Jr			S	Intramuscular	0.3 Mg, Once			Pfizer
					_					D.C.
	Epipen	Jr			S	Intramuscular	0.3 Mg, Once			Pfizer



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	Benadryl  A Received Date				С	Sublingual	12.5 N	⁄lg, Single			
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Aug-2017	13818492	EXPEDITED (15-DAY)			ОТ	GB-MYLANLA 2017M10464				Unknown	GBR
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Issue; Product Quality Issue	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Aug-2017	13842600	EXPEDITED (15-DAY)			ОТ	FI-MYLANLAI 2017M104846				Unknown	FIN
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Malfunction; Needle Issue	Epipen	Jr			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Aug-2017	13843913	EXPEDITED (15-DAY)			DE, OT	JP-PFIZER IN 2017338994	IC-		56 YR	Male	JPN
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Death	Epipen	0.3mg			S					Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Aug-2017	13845317	EXPEDITED (15-DAY)			LT, OT	US-MYLANLA 2017M104659				Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipen	Jr. Auto-Injector			S	Intramuscular	0.15 N	/lg, Once		Myl	an
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Aug-2017	13846581	EXPEDITED (15-DAY)			HO, OT	US-MYLANLA 2017M10472				Unknown	USA
Preferred Term	Produc	<u>&gt;t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>	



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Drug Ineffective	Epipen /	Auto-Injector			S	Intran	nuscular	0.3 Mg,	Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Aug-2017	13855852	NON-EXPEDITED			DE, OT		US-PFIZER INC 2017346856	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Rout	<u>te</u> <u>l</u>	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Dose Omission; Product Qua Issue					S			Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<b>Health</b>	<u>Prof</u>	Outcomes		Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Aug-2017	13857611	EXPEDITED (15-DAY)			ОТ		US-MYLANLABS 2017M1048708	S-			Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Rou	<u>:e</u> <u>l</u>	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose Epipen /	Auto-Injector			S	Intran	nuscular	0.3 Mg,	Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes		Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Aug-2017	13865206	NON-EXPEDITED					US-AEGERION PHARMACEUTI INC-AEGR00277				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Rou	<u>:e</u> <u>l</u>	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Allergy To Arthropod	Juxtapid				S	Oral		5 Mg, C	Qd		Ae	gerion
Sting; Dry Skin; Eczem Erythema; Hyperhidros					S	Oral		10 Mg,			Ae	gerion
Inappropriate Schedule Drug Administration; Peripheral Swelling; Ra Skin Discolouration; Sk Exfoliation; Urticaria	e Of Epipen ash;				S			1 Df, Si	ngle			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes		Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Aug-2017	13866218	EXPEDITED (15-DAY)			ОТ		SE-MYLANLABS 2017M1049149	S-			Unknown	SWE



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Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>	
Device Failure		300 Míkrógrömm; lyf, Lausn Í Áfylltum nna			S		Unk, Pı	m		My	Mylan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
16-Aug-2017	13790189	EXPEDITED (15-DAY)		0	Γ	JP-PFIZER 201731677	-		13 YR	Female	JPN	
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	Text	<b>Duration</b>	Mf	<u>.</u>	
Injection Site Injury	Epipen	0.3mg			S	Intramuscular	0.3 Mg	, Single		Pf	izer	
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
16-Aug-2017	13872316	NON-EXPEDITED				US-PFIZEF 201734861				Unknown	USA	
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mf	<u>r</u>	
Injection Site Pain	Epipen				S		Unk		Pfizer		izer	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
16-Aug-2017	13872360	EXPEDITED (15-DAY)		0	Γ	CA-PFIZEF 201735038				Female	CAN	
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	Mf	<u>r</u>	
Device Failure; Device Use Issue; Drug Dose Omission; Product Qualssue					S		Unk				izer	
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
16-Aug-2017	13872365	NON-EXPEDITED		LT	, OT	US-PFIZEF 201735029			Female US		USA	
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>Mf</u> ı	1	
Drug Ineffective	Epipen				S		Unk			Pf	izer	



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Aug-2017	13872741	EXPEDITED (15-DAY)			HO, OT	RU-PFIZ 2017352	ZER INC- 2847			Male	RUS
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Muscle Haemorrhage	Epipen				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Aug-2017	13874092	EXPEDITED (15-DAY)			DE, OT	JP-MYL 2017M1	ANLABS- 050035			Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Death	Epipen				S		Unk			М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Aug-2017	13875107	EXPEDITED (15-DAY)			HO, OT	RU-MYL 2017M1	ANLABS- 050084			Unknown	RUS
Preferred Term	Produc	<u>:t</u>	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Muscle Haemorrhage	Epipen				S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Aug-2017	13883481	EXPEDITED (15-DAY)			ОТ	MEDICA	ERNATIONAL ATION MS, LIMITED-		9 YR	Male	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product; Anxiety; Capi Nail Refill Test Abnorn Injection Site Haemorrhage; Injection Site Pain; Injection Site Swelling; Pain In Extremity; Pallor	llary nal; n	Jr			S						ternational edication System



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Aug-2017	13903330	EXPEDITED (15-DAY)			HO, OT	GB-MYLA 2017M104	_			Unknown	GBR
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Administration Site Discolouration; Infection; Injection Site Reaction	n	n Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Aug-2017	13866907	EXPEDITED (15-DAY)			HO, OT	GB-PFIZE 20173142			23 YR	Female	GBR
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Administration Site Discolouration; Infection; Injection Site Reaction	n	n			S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Aug-2017	13791818	EXPEDITED (15-DAY)			HO, LT, OT	CA-MYLAI 2017M104				Female	CAN
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose Epipe	n			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Sep-2017	13845325	EXPEDITED (15-DAY)			LT, OT	US-MYLAI 2017M104	-		61 YR	Female	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		Му	lan
	Epipe	n Auto-Injector			S					My	lan



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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	Age	Sex	Country
04-Sep-2017	13733659	EXPEDITED (15-DAY)	- I oditi		LT, OT	FR-MYLAN 2017M1040	LABS-	<u> </u>	<u> </u>	Unknown	FRA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mfr</u>	
Complication Of Devic Removal; Drug Ineffec Needle Issue					S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Sep-2017	13937771	NON-EXPEDITED				US-PFIZER 201737752	-			Female	USA
Preferred Term	Produc	<u>ot</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<b>Duration</b>	Mfr	
Injection Site Bruising; Nervousness	Epipen				S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Sep-2017	13941698	NON-EXPEDITED				US-PFIZER 201738198				Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Injection Site Coldness; Injection Sit Hypoaesthesia					S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13942305	EXPEDITED (15-DAY)			ОТ	CA-PFIZER 201738195			9 YR	Female	CAN
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	ge Text	<b>Duration</b>	Mfr	
Accidental Exposure T Product By Child; Injection Site Coldness; Injection Site Ischaemia; Injection Site Pain; Injection Site Pallor; Injection Site	ction n on	Jr			S	Intramuscular	0.3 N	/lg, Unk		Pfi	zer



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>	
07-Sep-2017	13903276	NON-EXPEDITED				US-PFIZER IN 2017360522	C-			Female	USA	
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	Text	<u>Duration</u>	Mfr	:	
Accidental Exposure T Product; Expired Prod Administered; Vasodilatation		n Jr			S		Unk			Pfi	zer	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
11-Sep-2017	13922032	NON-EXPEDITED				US-PFIZER IN 2017371089	C-			Female USA		
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	:	
Product; Expired Product; Expired Product; Administered; Injection Site Hypoaesthesia; Injection Site Paraesthesia; Injection Site Swelling; Wrong Technique In Product Usage Process	า						Unk					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control :	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
13-Sep-2017	13963315	NON-EXPEDITED				US- GLAXOSMITH US2017139403			53 YR	Female	USA	
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr		
Anxiety; Dysphagia; Dyspnoea; Gait Disturbance;	Enine	sta Solution For Infusion n (Adrenalin)			S S	Intravenous (not otherwise specified)	720 Mg	g, Z		Gl	axosmithkline	
Hypersensitivity; Naus Nervousness; Pruritus Tremor	sea;	•										



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

							-				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Sep-2017	13935905	EXPEDITED (15-DAY)			HO, LT, OT	HU-MYLAN 2017M1054	_			Female	HUN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	e Text	<b>Duration</b>	Mfr	
Brain Injury; Coma; Dr Ineffective; Dyspnoea	ug Epipen				S		2 Df,	Unk		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Sep-2017	13961546	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1056	_			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mfr	
Drug Ineffective	Epipen	Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Sep-2017	13973115	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2017M1055			48 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Drug Ineffective		Auto-Injector Auto-Injector			s s	Intramuscular	0.3 M	g, Prn		My My	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Sep-2017	13976261	NON-EXPEDITED				US-PFIZER 2017401084	-			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Dizziness; Feeling Abnormal; Fee Jittery; Palpitations					S		Unk			Pfiz	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Sep-2017	13036474	EXPEDITED (15-DAY)			HO, LT, OT	CA-MYLANI 2016M1055			8 YR	Unknown	CAN



Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage</u>	Text	<b>Duration</b>		<u>Mfr</u>
Device Failure; Drug D Omission	Oose Epipen				S	Intramuscular	Unk				Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Sep-2017	13983709	NON-EXPEDITED			ОТ	US-PFIZER 201739855	-		16 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Device Failure; Device Use Issue; Injection Si Haemorrhage; Needle Issue; Product Quality Issue; Product Storage Error	te				S	Intramuscular	0.3 Mg	ı, Prn			Pfizer
FDA Received Date	DA Received Date		Health Prof Outcomes		Mfr Control # 503B Facility		<u>Age</u>	<u>Sex</u>	Country		
19-Sep-2017	13988020	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1056			56 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		<u>Mfr</u>
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	, Once			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2017	13942401	EXPEDITED (15-DAY)			ОТ	US-PFIZER 201737871			1 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>		Mfr
ccidental Exposure To Epipen Jr roduct By Child; onjunctival Hyperaemia; yelid Haematoma; Injury orneal; Iris Injury; Lens isorder; Mydriasis; etinal Haemorrhage; etinal Tear; Tachycardia				S	Ophthalmic	Unk (1	:1000 Of 0.15mg)			Pfizer	



							•				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2017	13961144	EXPEDITED (15-DAY)		ОТ	Г	FI-PFIZEF 20173891			68 YR	Male	FIN
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>M</u> 1	<u>'r</u>
Device Failure; Device Use Issue; Drug Ineffective; Needle Iss		n			S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2017	13963046	NON-EXPEDITED		ОТ	Г	US-PFIZE 20173923	-			Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>M1</u>	<u>'r</u>
Drug Ineffective	Epipei	n 0.3mg			S		0.3 M	g, Unk		Р	fizer
	Epipei	n 0.3mg			S					fizer	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>ıtcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2017	13967368	NON-EXPEDITED		LT	, OT	US-PFIZE 20173924			48 YR	Female	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Drug Ineffective	Epipei	n			S	Intramuscular	0.3 M	g, Prn		Р	fizer
	Epipei	n			S					Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>ıtcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2017	13994488	EXPEDITED (15-DAY)		ОТ	Г	SE-MYLA 2017M10	_		25 YR	Female	SWE
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>M</u> 1	<u>'r</u>
Condition Aggravated;		n			S		Unk				ylan
Hypersensitivity; Incorr Dose Administered;	rect Deslo	ratadin			С		1 Pied	e		M	ylan
Needle Issue		ratadin ratadin red			C C C		10 Pie	eces		M	ylan ylan ylan
	Betap				С		1011				ylan

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# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Sep-2017 14009895 EXPEDITED (15				С					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Sep-2017	14009895	EXPEDITED (15-DAY)			LT, OT	CA-MYLAN 2017M1056				Female	CAN
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	Mf	<u>r</u>
Device Failure; Produc Storage Error	ct Epiper	ı			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2017	14010885	NON-EXPEDITED			ОТ	US-PFIZER 201741297				Female	USA
Preferred Term	Produ	ıct	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mf	<u>r</u>
Drug Ineffective; Expire Product Administered	ed Epiper	n Jr			S	Intramuscular	Unk			Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2017	14013936	EXPEDITED (15-DAY)			LT, OT	US-MYLAN 2017M1058	_		43 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 M	lg, Once		Sex Female  Mf  M  Sex Female  Mf  P  Sex Female  Mf  M  M  M  M  M  M  M  M  M  M  M  M	ylan
	Epiper	n Auto-Injector			S					M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Sep-2017	13497077	EXPEDITED (15-DAY)			HO, OT	US-MYLAN 2017M1025			53 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Drug Effect Incomplete Injection Site Haemorrhage	e; Epiper	n Auto-Injector			S	Intramuscular	0.3 M	lg, Once	Mylar		ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	Sex	Country
28-Sep-2017					ОТ	FR-MYLAN 2017M1055			67 YR	Male	FRA



						201404	. СРО. С						
Preferred Term	Produc	t	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	e Text	<b>Duration</b>	<u>M</u>	<u>fr</u>		
Anaphylactic Shock;	Epipen				S		Unk			N	lylan		
Device Failure; Drug Do Omission	ose Crestor				С		Unk			Sex Male  Mf My Ms Sex Female  Mf Mg	1ylan		
Citilodicii	Pariet				С		Unk			N	lylan		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	Sex	Country		
02-Oct-2017	13400517	EXPEDITED (15-DAY)		Н	O, OT	JP-MYLANLA 2017M10198			16 YR	Male	JPN		
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>		
Device Failure; Device					S	Intramuscular	0.3 Mg	g, Once		N	<b>l</b> ylan		
Use Issue; Needle Issu	ie Epipen				S		Unk			N	1ylan		
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	Sex	Country		
02-Oct-2017	14031416	EXPEDITED (15-DAY)		Lī	, OT	CA-MYLANL/ 2017M10487			42 YR Female		CAN		
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>		
Device Failure	Epipen				S		Unk			N	1ylan		
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country		
03-Oct-2017	14017274	EXPEDITED (15-DAY)		0.	Г	FR-PFIZER II 2017385274	NC-		67 YR	Male	FRA		
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u> ′	<u>fr</u>		
Anaphylactic Shock;	Epipen				S		Unk			Р	fizer		
Device Failure; Device Use Issue; Drug Dose	Crestor				С		Unk						
Omission; Product Qualissue	ality Pariet				С		Unk						
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country		
03-Oct-2017	14035216	NON-EXPEDITED				US-PFIZER I	NC-		Male USA				
						2017423205							

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#### FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

S Pfizer Accidental Exposure To Epipen Jr Intramuscular 0.15 Mg, Prn Product By Child; Anxiety; **Expired Product** Administered; Flushing FDA Received Date Case # **Health Prof Outcomes Case Type** Mfr Control # 503B Facility Sex Country <u>Age</u> **US-PFIZER INC-**05-Oct-2017 13650995 **EXPEDITED (15-DAY)** DE 31 YR Male USA 2017258315 **Preferred Term Product** Comp. **OTC** Role **Route Dosage Text Duration** Mfr Asthma: Device Failure: S Pfizer Epipen Unk Device Use Issue: Drug **Epipen** S Pfizer Dose Omission: С Salbutamol Sulfate Unk Hypersensitivity; Product С Quality Issue Breo Ellipta Unk C Diphenhydramine Hydrochloride Unk FDA Received Date Case # Case Type **Health Prof Outcomes** Mfr Control # 503B Facility Age Sex Country **GB-PFIZER INC-**05-Oct-2017 13984402 **EXPEDITED (15-DAY)** HO, LT, OT Female HUN 2017366025 **Preferred Term Product** Comp. OTC Role Route **Dosage Text** Duration Mfr S Brain Injury; Coma; Drug Epipen Pfizer Two Doses Ineffective; Dyspnoea FDA Received Date Case # **Case Type Health Prof Outcomes** Mfr Control # 503B Facility Sex Country <u>Age</u> **CA-PFIZER INC-**05-Oct-2017 14047732 EXPEDITED (15-DAY) LT. OT 42 YR Female CAN 2017083336 **Preferred Term Product OTC** Role **Route Dosage Text Duration** Mfr Comp. S Device Issue: Product Epipen Pfizer 0.3 Mg, As Needed Quality Issue; Underdose FDA Received Date Case # Case Type **Health Prof** Outcomes Mfr Control # 503B Facility Age Sex Country CA-PFIZER INC-06-Oct-2017 14057745 **EXPEDITED (15-DAY)** OT Female CAN 2017408624 **Preferred Term Product** Comp. **OTC** Role Route **Dosage Text** Duration Mfr



Device Failure: Device Use Issue; Drug Dose Omission; Feeling Jittery; Needle Issue: Product

Epipen Epipen S S

0.3 Mg, Unk 0.3 Mg, Unk

Pfizer Pfizer

Quality Issue

14061162

FDA Received Date Case #

**Case Type** 

**Health Prof Outcomes** OT

Mfr Control # JP-MYLANLABS- 503B Facility Age

Sex Male

Country

08-Oct-2017

**EXPEDITED (15-DAY)** 

S

2017M1062908

**Dosage Text** Duration

JPN

**Preferred Term** 

**Product** 

Comp. **OTC**  Role Route

Mfr

Drug Effect Incomplete

**Epipen** 

**Health Prof Outcomes** 

Mfr Control #

503B Facility

Age

20 YR

Sex

Mylan

Country

10-Oct-2017

FDA Received Date Case #

13708762

NON-EXPEDITED

Case Type

HO, LT, OT

S

**US-PFIZER INC-**2017285588

Intramuscular

Unk

42 YR

USA Male

**Preferred Term** 

**Product Epipen** 

Comp. OTC Role

**Route** 

**Dosage Text** 

0.3 Mg, Once

Duration

Mfr

Pfizer

Device Failure: Device Use Issue; Drug Ineffective: Product Quality Issue

FDA Received Date Case #

14075607

**Case Type** 

**Health Prof Outcomes** 

Mfr Control #

503B Facility

Age

Sex

Country

Intramuscular

**EXPEDITED (15-DAY)** 

S

US-MYLANLABS-2016M1059069

USA Female

**Preferred Term** 

10-Oct-2017

**Product** Epipen Auto-Injector Comp. **OTC** 

Role

**Route** 

**Dosage Text** 

**Duration** 

Mfr

Mylan

Device Failure

FDA Received Date Case #

14075644

**Case Type** 

**Health Prof Outcomes** 

Comp.

Unk Mfr Control #

**US-MYLANLABS-**

**503B Facility** 

Age

Sex

Country

**Preferred Term** 

10-Oct-2017

**Product** 

**EXPEDITED (15-DAY)** 

OTC Role Route

2017M1001198 **Dosage Text** 

54 YR

USA Female

Drug Ineffective

Epipen Auto-Injector

Prednisone

S С

0.3 Mg, Qd 90 Mg, Qd

**Duration** 

Mfr Mylan

Mylan

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		Hydroxy	zine			С		Unk		M	lylan
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	140756	75	EXPEDITED (15-DAY)				US-MYLANLA 2016M105781			Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Device Failure; Drug D	Oose	Epipen A	Auto-Injector			S	Intramuscular	0.3 Mg, Once		M	lylan
Omission		Epipen A	Auto-Injector			S	Intramuscular	0.3 Mg, Once		M	lylan
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	140756	888	EXPEDITED (15-DAY)				US-MYLANLA 2016M105937	=	3 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Accidental Exposure T Product By Child; Expi Product Administered		Epipen .	Jr. Auto-Injector			S	Intramuscular	0.15 Mg, Once		M	<b>l</b> ylan
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	140757	'16	EXPEDITED (15-DAY)				US-MYLANLA 2016M105946	=	19 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Device Failure; Drug D Omission	Oose	Epipen A	Auto-Injector			S	Intramuscular	0.3 Mg, Prn		M	lylan
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
10-Oct-2017	140757	'55	EXPEDITED (15-DAY)				US-MYLANLA 2016M105904			Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Device Failure		Epipen .	Jr. Auto-Injector			S	Intramuscular	0.15 Mg, Once		Mylan	
		Epipen .	Jr. Auto-Injector			S		-		N	1ylan

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# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14075781	EXPEDITED (15-DAY)				US-MYLAN 2016M105				Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D Omission; Intentional Product Misuse	ose Epipen	Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14075817	EXPEDITED (15-DAY)				US-MYLAN 2017M100	_		84 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product	o Epipen	Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14075818	EXPEDITED (15-DAY)				US-MYLAN 2017M100	_		64 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Anxiety; Expir Product Administered; Feeling Jittery	red	Auto-Injector			S	Intramuscular	0.3 M	lg, Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14075916	EXPEDITED (15-DAY)				US-MYLAN 2017M100			1 YR	Unknown	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	Mfr	
Off Label Use	Epipen	Jr. Auto-Injector			S		Unk N	Mg, Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14076011	EXPEDITED (15-DAY)				US-MYLAN 2017M1008				Female	USA



Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	Mf	<u>r</u>
Device Failure	Epiper	n Jr. Auto-Injector			S	Intramuscular	0.15 M	lg, Prn		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14076043	EXPEDITED (15-DAY)				US-MYLAN 2017M101				Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Circumstance Or Information Capable O Leading To Medication Error; Product Quality Issue	)f	n Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14076046	EXPEDITED (15-DAY)				US-MYLANLABS- 2017M1011971		64 YR	Female	USA	
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Device Failure; Produc Leakage	ct Epiper	n Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14076061	EXPEDITED (15-DAY)				US-MYLAN 2017M101	_		71 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Feeling Jittery;	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg	ı, Prn		М	ylan
Nervousness; Wrong Technique In Device	Epiper Zyrtec	n Auto-Injector			S C		Unk				ylan ylan
Usage Process	Levoce	etirizine			С		Unk				ylan
	Hydrox	xyzine			С		Unk			М	ylan
	l le colore	xyzine			С					N /	ylan



# FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol# <u></u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14076064	EXPEDITED (15-DAY)		0	Т	US-MYLAN 2017M1008	-		53 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure To Product; Injection Site Pain	o Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, (	Once		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	03B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14076158	EXPEDITED (15-DAY)				US-MYLAN 2017M1011			50 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage T	<u>'ext</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Device Failure; Expired Product Administered		Auto-Injector Auto-Injector			S S	Intramuscular Intramuscular	Unk 0.3 Mg, (	Once			ylan ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Oct-2017	14076199	EXPEDITED (15-DAY)				US-MYLAN 2017M1003			16 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<b>Duration</b>	<u>Mf</u>	<u>'r</u>
Accidental Exposure To Product; Chest Pain; Disturbance In Attentio Expired Product Administered; Feeling Jittery; Headache; Injection Site Bruising; Injection Site Pain		Auto-Injector			S		Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	03B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Oct-2017	14076633	EXPEDITED (15-DAY)		D	E	US-MYLAN 2011S1018			20 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage T	<u>'ext</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Anaphylactic Shock; Di	rug Epipen	Auto-Injector			S	Intramuscular	.3 Mg,Oı	nce		М	ylan



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Effect Incomplete	Epipen .	Auto-Injector Auto-Injector Auto-Injector	S S Health Prof Outcomes Mfr Control # 503B Facil						Mylan Mylan Mylan		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	13499871	NON-EXPEDITED			HO, OT	US-PFIZER 2017189896	-		53 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Drug Effect Incomplete Injection Site Haemorrhage	e; Epipen				S	Intramuscular	0.3 M	g, Once		P	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	13565227	EXPEDITED (15-DAY)			ОТ	FR-MYLANI 2017M1030	_		55 YR	Female	FRA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Expired Product Administered; Injection Site Haematoma; Vasoconstriction	uct				S	Intramuscular	Unk			М	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
12-Oct-2017	14077955	EXPEDITED (15-DAY)				US-MYLAN 2017M1013			81 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Expired Produ	uet	Auto-Injector			S		Unk				lylan
Administered; Injection Site Bruising; Injection Pain	n Cournac	din /00014802/			С		Unk			M	lylan
EDA Deseived Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date											



Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	<u>Route</u>	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Needle Issue	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078055	EXPEDITED (15-DAY)				US-MYLAN 2017M1015	-		3 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure To Product By Child; No Adverse Event; Product Quality Issue		n Jr. Auto-Injector			S	Intramuscular	0.15 N	/lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<b>Health</b>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078131	EXPEDITED (15-DAY)				US-MYLAN 2017M1018	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	0.3 M	g, Once		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078140	EXPEDITED (15-DAY)				US-MYLAN 2017M1020				Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product	o Epipe	n Auto-Injector			S	Intramuscular	Unk M	lg, Unk		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078154	EXPEDITED (15-DAY)				US-MYLAN 2017M1020	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epipe	n Auto-Injector			S		Unk			Му	lan



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14078179	EXPEDITED (15-DAY)				US-MYLAN 2017M102	_		2 YR	Male	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>.</u>
Device Failure; Drug D Omission; Injection Site Bruising; Injection Site Laceration; Needle Iss	te e	n Jr. Auto-Injector			S		Unk			M <u>y</u>	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14078180	EXPEDITED (15-DAY)				US-MYLAN 2017M102	_		12 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure; Drug Domission		n Auto-Injector			S	Intramuscular		g, Once			ylan
	Zyrtec				С	Oral	Unk, I	Monthly		My	ylan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078232	EXPEDITED (15-DAY)				US-MYLAN 2017M101	_			Female	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u> ı	<u>.</u>
Accidental Exposure T Product; Expired Prod Administered		n Auto-Injector			S	Intramuscular	Unk			My	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078239	EXPEDITED (15-DAY)				US-MYLAN 2017M102				Female	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>.</u>
Device Failure	Epiper	n Auto-Injector			S		Unk			My	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078689	EXPEDITED (15-DAY)				US-MYLAN	NLABS-		67 YR	Male	USA

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.

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Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Vomiting	Epipen	Auto-Injector			S		Unk			Myl	an
	Lisinop	ril			С		20 Mg	, Qd		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078707	EXPEDITED (15-DAY)				US-MYLAN 2017M1023	-		67 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Needle	e Epipen	Auto-Injector			S		0.3 Mg	յ, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078722	EXPEDITED (15-DAY)				US-MYLAN 2017M1023	-			Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<b>Duration</b>	Mfr	
Device Failure; Drug D Omission	ose Epipen	Auto-Injector			S		Unk U	nk, Once		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14078723	EXPEDITED (15-DAY)				US-MYLAN 2017M1022				Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	յ, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078725	EXPEDITED (15-DAY)				US-MYLAN 2017M1021	-		55 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	



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Drug Ineffective; Expir Product Administered; Product Storage Error		Auto-Injector			S	Intramu	ıscular	0.3 Mg	g, Once		Λ	<i>l</i> lylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	<u>I</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078728	EXPEDITED (15-DAY)					JS-MYLANLAE 2017M1022892				Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route		Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure	Epipen	Auto-Injector			S			Unk			N	⁄lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	<u>I</u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078742	EXPEDITED (15-DAY)					JS-MYLANLAE 2017M1023894				Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route		<u>Dosage</u>	e Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Malaise	Epipen	Auto-Injector			S			Unk			N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	<u> </u>	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078769	EXPEDITED (15-DAY)					JS-MYLANLAE 2017M1023907			21 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route		Dosage	e Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Device Failure; Drug	Epipen	Auto-Injector			S			Unk			N	/lylan
Effect Incomplete	Rifabut	tin			С			Unk			N	/lylan
	Xarelto	•			С			20 Mg	ı, Qd		N	⁄lylan
	Trilepta	al			С			100 M	lg, Bid		N	⁄lylan
	Cipro /	00697201/			С						N	/lylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	1	Mfr Control #	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078776	EXPEDITED (15-DAY)					JS-MYLANLAE 2017M1023916			8 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route		Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure	Epipen	Jr. Auto-Injector			S	Intramu	ıscular	0.15 N	/lg, Prn		N	/lylan



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FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503	B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078778	EXPEDITED (15-DAY)				US-MYLAN 2017M1023			54 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	1	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Accidental Exposure T Product; Back Disorde Device Failure; Injectio Site Haemorrhage	r;	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn			N	1ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # <u>503</u>	B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078891	EXPEDITED (15-DAY)				US-MYLAN 2017M1024				Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	į	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Device Failure; Drug D Omission; Rash	ose Epiper	n Auto-Injector			S		Unk Unk, Oı	nce		M	1ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol # 503	B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078920	EXPEDITED (15-DAY)				US-MYLAN 2017M1025			75 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	1	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Drug Ineffective	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg, Onc	ce		N	lylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contr	ol # 503	B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078922	EXPEDITED (15-DAY)				US-MYLAN 2017M1025	-			Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text		<b>Duration</b>	<u>M</u> :	<u>fr</u>
Device Failure	Epiper	n Auto-Injector			S		Unk			M	lylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contr	ol # 503	B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078925	EXPEDITED (15-DAY)				US-MYLAN 2017M1023				Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	<u>Role</u>	<u>Route</u>	Dosage Text		<b>Duration</b>	<u>M</u> :	<u>fr</u>



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Device Failure; Expired	d Epipei	n Auto-Injector			S	Intramuscular	0.3 Mg	, Prn		M	/lan
Product Administered	Epipei	n Auto-Injector			S					My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078932	EXPEDITED (15-DAY)				US-MYLAN 2017M1026			87 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	Text	<b>Duration</b>	Mf	<u> </u>
Device Failure	Epipei	n Auto-Injector			S	Intramuscular	0.3 Mg	, Prn		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078936	EXPEDITED (15-DAY)				US-MYLAN 2017M1024				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mf	
Device Failure; Drug D Omission	ose Epipei	n Auto-Injector			S	Intramuscular	Unk Uı	nk, Once		My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078945	EXPEDITED (15-DAY)				US-MYLAN 2017M1025			3 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	Text	<u>Duration</u>	Mf	
Device Use Error; No Adverse Event	Epipei	n Jr. Auto-Injector			S		Unk			My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078949	EXPEDITED (15-DAY)				US-MYLAN 2017M1025			31 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	Mf	
Device Failure	Epipei	n Auto-Injector			S	Intramuscular	0.3 Mg	, Once		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078953	EXPEDITED (15-DAY)				US-MYLANI 2017M1025			45 YR	Female	USA



Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Device Failur Injection Site Discolouration; Injection Site Hypoaesthesia	e;	n Auto-Injector			S	Intramuscular	Unk Unk, Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078954	EXPEDITED (15-DAY)				US-MYLAN 2017M1025	=	68 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure		n Auto-Injector n Auto-Injector			S S	Intramuscular	0.3 Mg, Once		-	rlan rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078955	EXPEDITED (15-DAY)				US-MYLAN 2017M1021	=	14 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<b>Duration</b>	Mfr	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg, Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078962	EXPEDITED (15-DAY)				US-MYLAN 2017M1024	=	39 YR	Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	<u>Role</u>	Route	Dosage Text	<b>Duration</b>	Mfr	
Drug Ineffective	Epiper	n Auto-Injector			S		0.3 Mg, Once		Му	rlan e
	Benad	ryl /00000402/			S		1 Df, Once		Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078964	EXPEDITED (15-DAY)				US-MYLAN 2017M1023		48 YR	Female	USA
Preferred Term	Produ	and the same of th	Comp.	отс	Role	Route	Dosage Text	Duration	Mfr	



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Device Failure; Injectio Site Pain	n Epipe	en Auto-Injector			S	Intramuscular	Unk Un	nk, Once		N	⁄lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078965	EXPEDITED (15-DAY)				US-MYLAN 2017M1024	_		56 YR	Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure	Epipe	en Auto-Injector			S	Intramuscular	Unk Un	nk, Once		N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078967	EXPEDITED (15-DAY)				US-MYLAN 2017M1026	_		40 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Device Failure; Needle Issue	Epipe Ritalii	en Auto-Injector n			S C	Intramuscular Oral	0.3 Mg, 20 Mg,				⁄lylan ⁄lylan
	Clarit	in /00413701/			С	Oral	10 Mg,			N	/lylan
	Pulmi	icort			С	Respiratory (inhalation)	_	2 Puffs, Bid		N	⁄lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078979	EXPEDITED (15-DAY)				US-MYLAN 2017M1024			7 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure; Injectio Site Laceration; Needle Issue; Scar		en Jr. Auto-Injector			S	Intramuscular	0.15 M	g, Once		N	<i>l</i> lylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14078988	EXPEDITED (15-DAY)				US-MYLAN 2017M1025				Female	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure; Injectio	n Epipe	en Auto-Injector			S	Intramuscular	0.3 Mg	, Prn		N	/lylan



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						Dotanoa i	topoit					
Site Bruising	Epipen Plavix	Auto-Injector			S C		75 Mg	, Qd		Mylan Mylan		
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14078998	EXPEDITED (15-DAY)				US-MYLAN 2017M1024	_		75 YR	Female	USA	
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>	
Accidental Exposure T Product; No Adverse Event	ō Epipen	Auto-Injector			S		Unk U	nk, Once		M	ylan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14078999	EXPEDITED (15-DAY)				US-MYLAN 2017M1026			13 YR	Male	USA	
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>	
Accidental Exposure T Product; Expired Product; Administered; Injection Site Bruising; Injection Injury	uct	Auto-Injector			S		Unk			M	ylan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14079002	EXPEDITED (15-DAY)				US-MYLAN 2017M1023	_			Female	USA	
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>	
Device Failure	Epipen	Auto-Injector			S		Unk			M	ylan	
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14079004	EXPEDITED (15-DAY)				US-MYLAN 2017M1023			59 YR	Female	USA	
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>	
					0							
Device Failure; Injection Site Bruising	on Epipen	Auto-Injector			S	Intramuscular	Unk			M	ylan	



	Bustar				С		Unk,	Гid		N	lylan
	Lasix /0	00032601/			С		Unk, (	Qd		N	/lylan
	Ambier	1			С		Unk, I	⊣s		N	/lylan
	Zyrtec				С		Unk, (	Qd		N	/lylan
	Novolo	g			С		5 lu, 7	Γid		N	/lylan
	Albuter	ol Sulfate			С	Respiratory (inhalation)	Unk, I	⊃rn		N	/lylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080046	EXPEDITED (15-DAY)				US-MYLANL 2017M10273	-		54 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>
Device Failure		Auto-Injector pertensives			S C	Intramuscular	0.3 M Unk	g, Once			1ylan 1ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080048	EXPEDITED (15-DAY)				US-MYLANL 2017M10275				Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosag	<u>e Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure To Product; Dizziness; Expired Product Administered; Hyperhidrosis; Injectior Site Hypoaesthesia; Palpitations		Auto-Injector			S	Intramuscular	Unk L	Jnk, Once		N	<b>1</b> Iylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080053	EXPEDITED (15-DAY)				US-MYLANL 2017M10273			3 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosag	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Accidental Exposure To Product By Child; Injec		Auto-Injector			S		Unk			N	<b>l</b> lylan

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	1	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
12-Oct-2017	14080085	EXPEDITED (15-DAY)				US-MYLANLAE 2017M1028768	-		36 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure	Epipe	n Auto-Injector			S	Intramuscular	Unk Uı	nk, Prn		ľ	Mylan
	Lisino	pril			С		2.5 Mg	ı, Qd		ľ	Mylan
	Carve	dilol			С		6.25 M			ľ	Mylan
	Digoxi	in			С		250 M			ľ	Mylan
	Buspii	rone			С		15 Mg	_		ľ	Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080146	EXPEDITED (15-DAY)				US-MYLANLAE 2017M1029498			3 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product By Child; Heal Rate Increased; Injecti Site Haemorrhage	rt	n Auto-Injector			S		0.3 Mg	g, Once		1	Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080157	EXPEDITED (15-DAY)				US-MYLANLAE 2017M1030085			3 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product By Child	o Epipe	n Jr. Auto-Injector			S	Intramuscular	0.15 M	lg, Prn		١	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	<u>!</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080158	EXPEDITED (15-DAY)				US-MYLANLAE 2017M1030326			51 YR	Female	USA
Preferred Term	Produ		Comp.	ОТС	Role	Route	Dosage	<b>T</b> 1	<u>Duration</u>		<u>lfr</u>



Device Failure; Drug D Omission	ose Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080170	EXPEDITED (15-DAY)				US-MYLAN 2017M1030	_		58 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage 1	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Urticaria	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080175	EXPEDITED (15-DAY)				US-MYLAN 2017M1030				Unknown	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 7	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
No Adverse Event; Off Label Use	Epiper	n Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080283	EXPEDITED (15-DAY)				US-MYLAN 2017M1033			10 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Injection Site Erythema	on Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg,	Once		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080322	EXPEDITED (15-DAY)				US-MYLAN 2017M1033			10 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage 7	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Injur Associated With Devic Needle Issue	у	n Jr. Auto-Injector			S	Intramuscular	0.15 Mg	ı, Prn		Му	lan



EDA Pagained Data	Coco #	Coco Type	Health	Dref	Outcomes	Mir Cont	ol#	E02D Ecciliar	Age	Cov	Country
FDA Received Date		Case Type	<u>neaith</u>	<u> 101</u>	<u>Outcomes</u>	Mfr Conti		503B Facility	Age	<u>Sex</u>	Country
12-Oct-2017	14080335	EXPEDITED (15-DAY)				US-MYLAN 2017M103			19 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	vlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14080336	EXPEDITED (15-DAY)				US-MYLAN 2017M103			58 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure; Drug D Omission	Oose Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Conti	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080340	EXPEDITED (15-DAY)				US-MYLAN 2017M103				Unknown	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		Му	rlan e
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14080346	EXPEDITED (15-DAY)				US-MYLAN 2017M103				Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen	Auto-Injector			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080357	EXPEDITED (15-DAY)				US-MYLAN 2017M103				Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Failure		Auto-Injector			S						<i>r</i> lan

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Note: If the field is blank, there is no data.

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080380	EXPEDITED (15-DAY)					LANLABS- 1033595			Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Anxiety; Expi Product Administered; Palpitations	red	n Auto-Injector			S		Unk			Му	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080387	EXPEDITED (15-DAY)					LANLABS- 1034859			Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission	Oose Epipe	n Auto-Injector			S		Unk			Му	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080436	EXPEDITED (15-DAY)					LANLABS- 1034280			Unknown	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Drug Effect Delayed	Epipe	n Auto-Injector			S		Unk			Му	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080456	EXPEDITED (15-DAY)					LANLABS- 1034875			Unknown	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epipe	n Auto-Injector			S		Unk			Му	an
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	14080463	EXPEDITED (15-DAY)					LANLABS- 1037394		16 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>Mfr</u>	



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Drug Ineffective	Ер	ipen Auto-Injector			S		Unk			Mylan		
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14080511	EXPEDITED (15-DAY)				US-MYLAN 2017M103			59 YR	Female	USA	
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>		
Drug Ineffective	Ер	ipen Auto-Injector			S	Intramuscular	0.3 M	g, Once		Му	lan	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14080655	EXPEDITED (15-DAY)				US-MYLAN 2017M103	_		60 YR	Female	USA	
Preferred Term	Pro	oduct	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>		
Device Failure	Ер	ipen Auto-Injector			S	Intramuscular	0.3 M	g, Prn		Му	lan	
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14080657	EXPEDITED (15-DAY)				US-MYLAN 2017M103				Female	USA	
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mfr</u>		
Device Failure	Ep	ipen Auto-Injector			S		Unk			Му	lan	
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14080667	EXPEDITED (15-DAY)				US-MYLAN 2017M103				Unknown	USA	
Preferred Term	Pr	oduct	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>		
Accidental Exposure T	о Ер	ipen Auto-Injector			S		Unk			Му	lan	
Product	Sy	nthroid			С		Unk			Му	lan	
	Mu	ultivitamin /00097801/			С		Unk			My	lan	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
12-Oct-2017	14080681	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M103			7 YR	Male	USA	



Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Injection Site Laceration Needle Issue	on; Epiper	n Jr. Auto-Injector			S	Intramuscular	0.15 Mg, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol # 503B Fac	ility Age	<u>Sex</u>	Country
12-Oct-2017	14081783	EXPEDITED (15-DAY)				US-MYLAI 2017M104	=	18 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Duration</u>	Mfr	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 Mg, Prn		Myl	an
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol # 503B Fac	ility Age	<u>Sex</u>	Country
12-Oct-2017	14081800	EXPEDITED (15-DAY)				US-MYLAI 2017M104	_	2 YR	Female	USA
Preferred Term	Produ	ıct	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>Mfr</u>	
Device Failure	Epiper	n Jr. Auto-Injector			S	Intramuscular	0.15 Mg, Prn		Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Cont	rol # 503B Fac	ility Age	<u>Sex</u>	Country
12-Oct-2017	14081868	EXPEDITED (15-DAY)				US-MYLAI 2017M104	_		Unknown	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective		n Auto-Injector otic /00011701/			S C	Intramuscular	0.3 Mg, Prn Unk		Myl Myl	
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol # 503B Fac	ility Age	<u>Sex</u>	Country
12-Oct-2017	14081908	EXPEDITED (15-DAY)				US-MYLAI 2017M104	=		Unknown	USA
Preferred Term	Produ	ıct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D Omission	Oose Epiper	n Jr. Auto-Injector			S		Unk		Myl	an



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FDA Received Date	Case #	Case Type	Hoolth	Drof (	Outcomes	Mfr Contro	ol # 503B Facility	Ago	Sex	Country
12-Oct-2017	1408196			<u> </u>	<u>Juicomes</u>	US-MYLANI 2017M1048	ABS-	<u>Age</u>	<u>Sex</u> Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product; Expired Product; Administered; No Adve Event	uct	pipen Jr. Auto-Injector			S		Unk		1	Mylan
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	1408252	3 EXPEDITED (15-DAY)				US-MYLANI 2017M1052	=		Male	USA
Preferred Term	Ē	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Injection Site Pain; Inju Associated With Devic Needle Issue; Product Quality Issue	e;	pipen Jr. Auto-Injector			S		Unk		1	<i>I</i> lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	1408268	9 EXPEDITED (15-DAY)				US-MYLANI 2017M1054			Male	USA
Preferred Term	E	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Accidental Exposure T Product; Injection Site Coldness; Injection Sit Hypoaesthesia		pipen Auto-Injector			S		Unk		1	<i>I</i> lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Oct-2017	1408275	9 EXPEDITED (15-DAY)				US-MYLANI 2017M1055	=	55 YR	Male	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Device Failure; Drug D Omission		pipen Auto-Injector			S	Intramuscular	0.3 Mg, Once			Mylan
Omission	C	Sabapentin			С		Unk		ľ	Mylan



	Nexium /01479302/				С		Unk		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Oct-2017	13541664	EXPEDITED (15-DAY)		Ľ	т, от	US-MYLANL 2017M10277		18 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D		Auto-Injector			S	Intramuscular	Unk Unk, Once		Му	lan
Omission; Drug Effect Decreased; Expired	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Unk		Му	lan
Product Administered	Melator	nin			С		Unk, Prn, Bedtime		Му	lan
	Claritin	/00917501/			С		Unk, Prn		Му	lan
	Symbio	ort			С		2 Df, Qd		Му	lan
	Ventolii	n Hfa			С		2 Df, Prn, Q6hrs		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Oct-2017	14081772	DIRECT	Υ						Unknown	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Dispensing Error	Epipen Epipen				S S					
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Oct-2017	14097947	EXPEDITED (15-DAY)				US-MYLANL 2017M10438		68 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D Omission	Dose Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Once		Му	lan
EDA Bessived Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
FDA Received Date						US-MYLANLABS- 2017M1047248			Female	USA
17-Oct-2017	14097954	EXPEDITED (15-DAY)				2017M10472	248			



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Device Failure	Epipen	Auto-Injector			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Oct-2017	14099352	NON-EXPEDITED			LT, OT	US-PFIZER I 2017212415	NC-		18 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure; Device	Epipen				S	Intramuscular	Unk U	nk, Once		Pf	fizer
Use Issue; Drug Dose Omission; Drug Effect	Epipen				S	Intramuscular	0.3 Mg	g, Unk		Pf	fizer
Decreased; Expired	Melaton	in			С		-	Prn, Bedtime			
Product Administered;	Claritin				С		Unk, F	Prn			
Product Quality Issue	Symbic	ort			С		2 Df, C				
	Ventolin	Hfa			С		•	Prn, Q6hrs			
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Oct-2017	13585823	EXPEDITED (15-DAY)			ОТ	FR-PFIZER I 2017232840	NC-		55 YR	Female	FRA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Accidental Exposure To Product; Expired Produ Administered; Injection Site Haematoma; Vasoconstriction	ıct				S	Intramuscular	Unk			Pf	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Oct-2017	14057313	NON-EXPEDITED			DE, OT	US-PFIZER I K201101077			20 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
Device Failure; Device Use Issue; Drug Dose Omission; Drug Ineffective; Needle Issu Product Quality Issue					S	Intramuscular	0.3 Mg	g, Once		Pf	fizer



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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Oct-2017	13418084	EXPEDITED (15-DAY)		ļ	НО	JP-PFIZEF 20171471;	_		73 YR	Female	JPN
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>otc</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Issue; Drug Dose Omission; Product Qua Issue		n 0.3mg			S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	14112027	NON-EXPEDITED				US-PFIZE 20174540	-			Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Tremor	Epiper	า			S		0.3 N	lg, Once		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Oct-2017	14117551	NON-EXPEDITED				US-MYLAI 2017M106			68 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epiper	n Auto-Injector			S	Intramuscular	0.3 N	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Oct-2017	14121277	NON-EXPEDITED				US-MYLAI 2017M105				Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Produ Administered		n Auto-Injector			S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Oct-2017	14121470	NON-EXPEDITED				US-MYLAI 2017M106				Male	USA

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Preferred Term	Produc	t	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product By Child; Anxi Expired Product Administered; Flushing	ety;	Jr. Auto-Injector			S	Intramuscular	0.15 M	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Oct-2017	14121867	EXPEDITED (15-DAY)		D	E	US-MYLA 2017M106				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug D Omission		Auto-Injector Auto-Injector			S S		Unk			My My	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Oct-2017	14133564	EXPEDITED (15-DAY)		H	O, OT	CA-MYLA 2017M105				Male	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	<u>Dosage</u>	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug D Omission	ose Epipen Epipen				S S		Unk			My My	
FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Oct-2017	13428905	EXPEDITED (15-DAY)		Н	0	JP-MYLAI 2017M102	-		73 YR	Female	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device Issue; Drug Dose Omission; Product Qual Issue					S		Unk			My	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Oct-2017	14142718	EXPEDITED (15-DAY)		D	E, HO, LT	OT GB-PFIZE 20174600			13 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	



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Cardiac Arrest; Expired Product Administered	d Epipen				S		Unk			F	Pfizer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Oct-2017	14145648	EXPEDITED (15-DAY)			DE, HO, LT,	OT GB-MYLAN 2017M1067			13 YR	Male	GBR
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Cardiac Arrest; Expired Product Administered	d Epipen				S		Unk			N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	14134880	EXPEDITED (15-DAY)			ОТ	US-MYLAN 2017M1067	-		13 YR	Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Device Failure; Drug D Omission	ose Epipen	Auto-Injector			S	Intramuscular	0.3 Mg	g, Once		N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
06-Nov-2017	14162143	EXPEDITED (15-DAY)			ОТ	PHHY2017	GB162350			Female	GBR
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Systemic Mastocytosis	s Omepr	azole			S	Unknown	40 Mg	, Qd		1	Novartis
	Ranitid	ine			S	Unknown	150 M	g, Bid			
	Sodiun	n Clodronate			S	Unknown	1040 ľ	Иg, Qd			
	Prednis	solone			S	Unknown	10 Mg	, Qd			
	Sodiun	n Cromoglycate			S	Oral					
	Cyclizii	ne			S	Unknown	50 Mg	, Tid			
	Epipen				S	Unknown	Unk U	nk, Prn			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	Age	<u>Sex</u>	Country
06-Nov-2017	14163260	NON-EXPEDITED			DE, OT	US-PFIZER K20090028	-			Female	USA



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Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>		<u>Mfr</u>
Device Failure; Device Use Issue; Drug Dose Omission; Drug Ineffective; Malaise; Needle Issue; Product Quality Issue	•	n			S	0.3 Mg, Single				Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Nov-2017	14175785	EXPEDITED (15-DAY)		I	DE	US-PFIZER II K200800145	NC-	65 YR	Male	ITA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>		<u>Mfr</u>
Drug Ineffective; Underdose	Epipe Epipe Epipe Epipe Bente	n Jr n Jr n Jr			S S S S S	Intramuscular	165 Ug, Single Unk			Pfizer Pfizer Pfizer Pfizer
	Bente Bente Trime Trime Trime	lan ton ton			S S S S		Unk			
FDA Received Date		Case Type	Health	Prof (	Outcomes	Mfr Control	<u>Age</u>	<u>Sex</u>	Country	
10-Nov-2017	14177871	EXPEDITED (15-DAY)		(	ОТ	JP-MYLANLA 2017M105166		73 YR	Male	JPN
Preferred Term	<u>Produ</u>	uct	Comp.	<u>otc</u>	Role	Route	Dosage Text	<b>Duration</b>		<u>Mfr</u>
Device Failure; Device Use Issue; Drug Dose Omission; Product Qua	Injecto	n (Epinephrine) Auto or 0.3 Mg ec			s C		Unk 1 Df, 1x/Day			Mylan Mylan
Issue	Febur	ic			С		1 Df, 1x/Day			Mylan
	Grima				С		1 Df, 3x/Day			Mylan
	Polysi				С		1 Df, 3x/Day			Mylan
	Camo	stat			С		1 Df, 3x/Day			Mylan



	Loxop	rofen			С		1 Df, 1x/D	ay		M	ylan
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contro	ol # <u>50</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Nov-2017	14180005	NON-EXPEDITED		(	TC	US-PFIZER 2017477196	-			Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	Mf	1
Blood Pressure Incread Device Failure; Device Use Issue; Heart Rate Increased; Needle Issu	Epipe				S S	Transdermal	0.3 Mg, P Unk	rn			izer izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol # 50	03B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Nov-2017	13894397	EXPEDITED (15-DAY)		ŀ	Ю	JP-MYLANI 2017M1051	-		58 YR	Male	JPN
Preferred Term			Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	Mf	ſ
Device Failure; Device	e Failure; Device Epipen (Epinephrine) Auto				S		Unk			M	ylan
Use Issue; Expired De Used; Product Quality	Epipe	or 0.3 Mg n (Epinephrine) Auto			S		Unk			M	ylan
Issue	Epipe	or 0.3 Mg n (Epinephrine) Auto or 0.3 Mg			S		Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control # 503B Facility			<u>Age</u>	<u>Sex</u>	Country
13-Nov-2017	14099234	EXPEDITED (15-DAY)		(	T	AU-MYLAN 2017M1063			7 YR	Male	AUS
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	Mf	<u>.</u>
Device Failure; Device Malfunction	Epipe Injecto	n Jr Adrenaline Auto- or			S	Intramuscular	Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	<u>ol #</u> 50	03B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Nov-2017	14183677	NON-EXPEDITED				US-PFIZER 201748787				Unknown	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>ext</u>	<b>Duration</b>	Mf	<u>.</u>
Arthralgia; Expired	ıralgia; Expired Epipen				S		Unk			Pf	izer

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Product Administered											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control #	ŧ	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
14-Nov-2017	14188017	EXPEDITED (15-DAY)		(	OT	US-MYLANLAE 2017M1070811	_		12 YR	Female	e USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Device Failure	Epipen /	Auto-Injector			S	Intramuscular	0.3 Mg	ı, Once			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control #	<u>ŧ</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Nov-2017	14188034	EXPEDITED (15-DAY)		[	DE, OT	IT-MYLANLAB K200800145	S-PF-		65 YR	Male	ITA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Device Malfunction; Dr Ineffective; Product	Eninen				s s	Intramuscular	165 M	cg,Total			Mylan Mylan
Quality Issue; Underdo	se Bentelai	n			S	Unknown	Unk				Mylan
	Trimeto	n /00072502/			S	Unknown	Unk				Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Control #	ŧ	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Nov-2017	14195277	EXPEDITED (15-DAY)		[	DE, OT	DK-PFIZER IN K200701131	C-		70 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Cardiac Arrest; Device	1 1 -				S	Subcutaneous	0.3 Mg	ı, As Needed			Pfizer
Failure; Device Use Iss Drug Ineffective; Produ					S	Subcutaneous	0.3 Mg	, As Needed			Pfizer
Quality Issue		in /00003901/			S	Intravenous (not otherwise specified)	Unk				
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Control #	<u> </u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Nov-2017	14196668	EXPEDITED (15-DAY)		ŀ	НО	ZA-MYLANLAE 2017M1071794	-			Male	ZAF
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		Mfr
Device Failure; Underc	dose Epipen				S		Unk				Mylan



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Nov-2017	14029939	EXPEDITED (15-DAY)		0	т	JP-MYLANL 2017M10616	-		60 YR	Male	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>		<u>Mfr</u>
Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	Epipen				S		Unk				Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Nov-2017	14201735	NON-EXPEDITED		0	ıΤ	US-PFIZER 2017490659				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>		Mfr
Device Failure; Device Use Issue; Drug Ineffective; Product Quality Issue	Epipen				S		Unk				Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2017	14202598	EXPEDITED (15-DAY)		D	E, LT, OT	GB-INTERN MEDICATIO SYSTEMS, I 20345	N		70 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>		Mfr
Cardiac Arrest; Death; Drug Ineffective; Pulse	Adrenali	n			S	Intravenous (not otherwise specifie	ed)				International Medication System
Absent	Adrenali Epipen	n			S S	Intramuscular	•				
	Epipen				S	Intramuscular					
	Epipen				S	Intramuscular					
	Epipen				S	Intramuscular					
	Epipen				S	Intramuscular					



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Nov-2017	14205748	EXPEDITED (15-DAY)		(	OT	GB-PFIZER I 2017121537	INC-		3 YR	Male	GBR
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Laceration; Pain; Scar; Wrong Technique In Product Usage Proces	Eninen				s s		Unk				fizer fizer
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Nov-2017	14208637	EXPEDITED (15-DAY)		L	_T, OT	CA-MYLANL/ 2017M10611	-			Female	CAN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Device Failure; Drug D Omission	ose Epipen				S		Unk			M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
21-Nov-2017	14209628	NON-EXPEDITED				US-PFIZER I 2017499106	NC-			Male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M1</u>	<u>ir</u>
Accidental Exposure T Product; Expired Product Administered					S		Unk			Р	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14177886	EXPEDITED (15-DAY)		[	DE, HO, OT	CH-MYLANL 2017M10716				Male	CHE
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>	<u>M</u> 1	<u>ir</u>
Respiratory Distress	Epipen				S		Unk			M	lylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Contro	<u>  #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Nov-2017	14213203	EXPEDITED (15-DAY)		(	OΤ	CA-MYLANL/ 2017M10721			4 YR	Female	CAN



Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	Dura	ation	Mfr
Device Failure	Epipen .	Jr			S		Unk			Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol # 503E	3 Facility Age	<u>Sex</u>	Country
22-Nov-2017	14213314	EXPEDITED (15-DAY)			LT, OT	CA-MYLA 2017M10	NLABS- 66958		Fema	le CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Dura</u>	ation	<u>Mfr</u>
Device Failure	Epipen				S		Unk			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol # 503E	3 Facility Age	<u>Sex</u>	Country
22-Nov-2017	14213381	EXPEDITED (15-DAY)			LT	US-MYLA 2017M10			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Dura</u>	ation .	<u>Mfr</u>
Hypersensitivity; Respiratory Arrest	Epipen /	Auto-Injector			S		Unk, Prn			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Con	trol # 503E	3 Facility Age	<u>Sex</u>	Country
22-Nov-2017	14214119	EXPEDITED (15-DAY)			ОТ	CA-PFIZE 20174837			Male	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	Dura	ation	<u>Mfr</u>
Device Failure; Device Use Issue; Drug Dose Omission; Product Qua Issue					S					Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Con	trol # 503E	3 Facility Age	<u>Sex</u>	Country
26-Nov-2017	14015823	EXPEDITED (15-DAY)			ОТ	JP-MYLA 2017M10		71 Y	'R Male	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Dura</u>	ation	<u>Mfr</u>
Device Failure; Device					S	Intramuscular	0.3 Mg, Onc	e		Mylan
Use Issue; No Adverse Event; Product Quality Issue		atin			С	Oral	2 Mg, Qd			Mylan



	Amlodipine  Received Date Case # Case Type				С	Oral	5 Mg, Qd			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contro	ol # 503E	B Facility Ac	ge <u>Se</u>	<u>x</u>	Country
26-Nov-2017	14225783	DIRECT		L	.T			42	YR Fe	male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Du</u>	<u>ıration</u>	<u>Mfr</u>	
Device Failure; Device Malfunction	Epipen Allergy Birth Co Vitamin	ontrol			\$ C C					Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Contro	ol # 503E	B Facility Ag	<u>je Se</u>	<u>x</u>	Country
28-Nov-2017	14191245	EXPEDITED (15-DAY)		[	DE, HO, OT	CH-PFIZER 2017486549			Ma	ale	CHE
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<u>Du</u>	<u>ıration</u>	<u>Mfr</u>	
Respiratory Distress	Epipen				S		Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contro	ol # 503E	3 Facility Ac	ge <u>Se</u>	<u>x</u>	Country
28-Nov-2017	14232052	EXPEDITED (15-DAY)		C	TC	CA-MYLAN 2017M1071			Ma	ale	CAN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<u>Du</u>	<u>ıration</u>	<u>Mfr</u>	
Device Failure; Drug D Omission	Oose Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof C	Outcomes	Mfr Contro	ol # 503E	B Facility Ac	<u>je Se</u>	<u>x</u>	Country
30-Nov-2017	12729044	EXPEDITED (15-DAY)		[	DE	US-MYLAN 2016M1037		17	YR Ma	ale	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	<u>Role</u>	Route	<b>Dosage Text</b>	<u>Du</u>	<u>ıration</u>	<u>Mfr</u>	
Device Failure; Device Use Issue; Drug Dose Omission; Product Qualssue		Auto-Injector			S	Intramuscular	Unk, Prn			Myl	an



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Dec-2017	14080530	NON-EXPEDITED				US-MYLANLAI 2017M103786	_		Male	USA
Preferred Term	<u>Produ</u>	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Device Failure; No Adverse Event	Epipe	n Jr. Auto-Injector			S		Unk			Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Dec-2017	13243324	EXPEDITED (15-DAY)			НО	ALCN2017CA001343		52 YR	Male	CAN
Preferred Term	Produ	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Hypersensitivity	Vigam	nox			S	Ophthalmic	Unk Unk, Tid			
	Betop	tic			S	Ophthalmic	Unk Unk, Qd			
	Olopa	tadine			S	Ophthalmic				
	Amloo	dipine			S	Oral	10 Mg, Qd			
	Besiva	ance			S	Ophthalmic	Unk Unk, Tid			
	Cialis				S	Unknown				
	Epipe	n Jr			S	Intramuscular	Unk			
	Nasor	nex			S		2 Df, Qd			
	Predn	isolone "Ratiopharm"			S	Unknown	Unk Unk, Qid			
	Predn	isolone "Ratiopharm"			S	Unknown	Unk Unk, Tid			
	Predn	isolone "Ratiopharm"			S	Unknown	Unk Unk, Bid			
	Predn	isone			S	Unknown	50 Mg, Tid			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Dec-2017	14252617	EXPEDITED (15-DAY)			DE	JP-PFIZER INC- 2017518542		68 YR	Male	JPN
Preferred Term	Produ	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Death	Epipen 0.3mg				S					Pfizer



							•				
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Dec-2017	14260184	EXPEDITED (15-DAY)		I	DE, OT	JP-PF 20175	IZER INC- 20304		80 YR	Male	JPN
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfı</u>	
Death	Epipen (	).3mg			S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Dec-2017	14260247	EXPEDITED (15-DAY)		1	DE, OT	JP-PF 20175	IZER INC- 20310		64 YR	Female	JPN
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u> ı	_
Death	Epipen (	).3mg			S					Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof 9	<u>Outcomes</u>	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Dec-2017	14260386	EXPEDITED (15-DAY)		(	ОТ		YLANLABS- 11076268			Female	CHE
Preferred Term	Product	<u>I</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mfı</u>	<u>:</u>
Device Malfunction; Underdose	Epipen				S					My	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2017	14033609	EXPEDITED (15-DAY)		I	НО		/LANLABS- 11061994			Female	AUS
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfı</u>	[
Device Failure; Drug Ineffective; Underdose	Epipen				S		300m	cg/2ml, Unk		My	/lan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2017	14264330	NON-EXPEDITED				US-JA 00848	ZZ-2014-US- 7		53 YR	Female	USA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u> ı	[
Diplopia; Disorientation Drug Resistance; Eye	n; Xyrem				S	Oral	3g, Bi	d		Ja	zz

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						Detailed P	report				
Pain; Fatigue; Milk Alle		า			S	Oral	3.75g	, Bid		J	azz
Muscle Spasms; Pove Of Speech; Rash; Visio Blurred	on Epipe	n			S S					J	azz
Sidi. Ou	Xolaiı				С	Subcutaneous	Unk				
	Potas				С	Oral	10 Me	eq, Qd			
	Estra				С	Oral	2 Mg,	Qd			
	Hydro	chlorothiazide			С	Oral	12.5 N	Mg, Qd			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Dec-2017	14274815	EXPEDITED (15-DAY)		Н	)	US-MYLANL 2017M10773			2 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Cough; Off Label Use; Scratch; Skin Discolouration; Urticar Wrong Technique In Product Usage Proces	ia;	n Jr. Auto-Injector			S		Unk			N	<i>I</i> lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Dec-2017	14276544	EXPEDITED (15-DAY)		0	Γ	CA-MYLANL 2017M10305				Female	CAN
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Drug Effect Delayed	Epipe	n			S	Intramuscular	0.3 M	g, Once		N	Nylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Dec-2017	14280494	EXPEDITED (15-DAY)		Н	)	US-PFIZER 2017531946			2 YR	Male	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Cough; Off Label Use; Scratch; Skin Discolouration; Urticar Wrong Technique In Product Usage Proces	ia;	n Jr			S		Unk			F	Pfizer



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
13-Dec-2017	14226204	EXPEDITED (15-DAY)		Lī	Γ	US-PFIZER 2017504891				Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Hypersensitivity; Respiratory Arrest	Epipen				S		Unk, A	As Needed (Prn)		F	Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Dec-2017	14287689	NON-EXPEDITED				US-MYLANL 2017M10787				Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Expired Product Administered; No Adve Event; Wrong Techniq	erse	Jr. Auto-Injector			S	Intramuscular				Λ	⁄/lylan
In Product Usage Prod											
	cess	Case Type	Health	Prof O	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
In Product Usage Prod	cess	Case Type EXPEDITED (15-DAY)	Health		utcomes E, OT	Mfr Contro AU-PFIZER 2017126206	INC-	503B Facility	<u>Age</u>	<u>Sex</u> Male	<u>Country</u> AUS
In Product Usage Prod FDA Received Date	Case #	EXPEDITED (15-DAY)	Health Comp.		_	AU-PFIZER	INC-	•	Age  Duration	Male	
In Product Usage Prod FDA Received Date 15-Dec-2017	Case # 13378022 Produc	EXPEDITED (15-DAY)		D	E, OT	AU-PFIZER 2017126206	INC-	•	_	Male	AUS
In Product Usage Prod FDA Received Date 15-Dec-2017 Preferred Term	Case # 13378022  Produce Epipen	EXPEDITED (15-DAY)	Comp.	OTC	E, OT	AU-PFIZER 2017126206 Route	Dosage Unk	•	_	Male	AUS
In Product Usage	Case # 13378022  Produce Epipen	EXPEDITED (15-DAY)	Comp.	OTC	E, OT  Role S  utcomes	AU-PFIZER 2017126206 Route Intramuscular	Dosage Unk  INC-	e Text	<u>Duration</u>	Male M	AUS  Offizer  Country
In Product Usage Prod FDA Received Date 15-Dec-2017 Preferred Term Death; Drug Ineffective FDA Received Date	Case #  13378022  Product Epipen  Case #	EXPEDITED (15-DAY)  Ct  Case Type  NON-EXPEDITED	Comp.	OTC Prof O	E, OT  Role S  utcomes	AU-PFIZER 2017126206  Route Intramuscular  Mfr Contro	Dosage Unk  INC-	E Text  503B Facility	<u>Duration</u>	Male  M  F  Sex  Unknown	AUS  Officer  Country
In Product Usage Product In Product Usage Product In Product Usage Product In Product In Inc. 15-Dec-2017  Preferred Term  Death; Drug Ineffective Inc. 15-Dec-2017	Produce Epipen  Case #  13378022  Produce Epipen  Case #  14289743	EXPEDITED (15-DAY)  Ct  Case Type  NON-EXPEDITED	Comp.  Health	OTC  Prof O	Role S utcomes	AU-PFIZER 2017126206  Route  Intramuscular  Mfr Contro  US-PFIZER 2017531945	Dosage Unk  INC-	E Text  503B Facility	<u>Duration</u>	Male  Male  Sex  Unknown	AUS  Offizer  Country  USA
In Product Usage Prod FDA Received Date 15-Dec-2017  Preferred Term Death; Drug Ineffective 15-Dec-2017  Preferred Term Drug Ineffective	Produces  Case #  13378022  Produce Epipen  Case #  14289743  Produce	EXPEDITED (15-DAY)  Ct  Case Type  NON-EXPEDITED	Comp.  Health Comp.	OTC  Prof O OTC	Role S utcomes T	AU-PFIZER 2017126206  Route  Intramuscular  Mfr Contro  US-PFIZER 2017531945  Route	Unk  Dosage  Unk  Dosage  Unk	E Text  503B Facility	<u>Duration</u>	Male  Male  Sex  Unknown	AUS  Ifr  Pfizer  Country  USA
In Product Usage Prod FDA Received Date 15-Dec-2017  Preferred Term Death; Drug Ineffective 15-Dec-2017  Preferred Term Drug Ineffective	Produce Epipen  Case #  13378022  Produce Epipen  Case #  14289743  Produce Epipen	EXPEDITED (15-DAY)  Ct  Case Type  NON-EXPEDITED	Comp.  Health Comp.	OTC  Prof O OTC  Prof O	Role S utcomes T Role S	AU-PFIZER 2017126206  Route  Intramuscular  Mfr Contro  US-PFIZER 2017531945  Route  Intramuscular	Unk  Dosage  Unk  Dosage  Unk  Dosage  Unk  Dosage	503B Facility	Duration  Age  Duration	Male  M  F  Sex  Unknown  M	AUS  AUS  Country USA  Ifr  Pfizer  Country  Country

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Note: If the field is blank, there is no data.

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Death; Drug Administration Error	Epipen				S		1 Df,	Single		Pfi	zer
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Dec-2017	14292870	EXPEDITED (15-DAY)		D	E, OT	JP-MYLANL 2017M10778			64 YR	Female	JPN
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	:
Death	Epipen				S		Unk			Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Dec-2017	14292878	EXPEDITED (15-DAY)		D	E, OT	JP-MYLANL 2017M10778			80 YR	Male	JPN
Preferred Term	Product	<u>I</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Death	Epipen				S		Unk			Му	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof C	utcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Dec-2017	14293152	EXPEDITED (15-DAY)		C	T	US-PFIZER 2017537955	INC-			Female	USA
Preferred Term	Product	<u> </u>	Comp.	<u>OTC</u>	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Accidental Exposure T Product; Injury Associa With Device; Product Quality Issue; Sensory Loss	ated				S	Intramuscular	Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Dec-2017	13982270	EXPEDITED (15-DAY)		C	T	NL-MYLANL 2017M10586	_		14 YR	Female	NLD
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	Mfr	
Drug Ineffective; No Adverse Event	Oplossin	00 Microgram, ng Voor Injectie In ulde Pen			S		1 Mg/	MI, Unk		Му	/lan



FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Dec-2017	13670527	EXPEDITED (15-DAY)		(	ОТ	FI-MYLANL 2017M1036				Female	FIN
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epipen Injector	(Epinephrine) Auto 0.3 Mg			S		Unk			Myl	an
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Dec-2017	14298415	EXPEDITED (15-DAY)		I	НО	AU-MYLAN 2017M1077				Female	AUS
Preferred Term	Produc	<u>:t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Asthma	Epipen				S		Unk			Myl	an
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Dec-2017	14307361	NON-EXPEDITED				US-PFIZEF 201753609			18 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Dihydrotestosterone Increased	Epipen	0.3mg			S	Intramuscular	1 Df, \$	Single		Pfiz	er
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14307531	NON-EXPEDITED				US-PFIZEF 201753784				Unknown	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Injury Associated With Device	Epipen	Jr			S	Intramuscular	Unk			Pfiz	er
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Dec-2017	14310160	EXPEDITED (15-DAY)		(	ОТ	US-PFIZEF 201753783				Female	USA
Preferred Term	Produc	•	Comp.	OTC	Role	Route	Dosage		<b>Duration</b>	Mfr	



Ear Swelling; Pruritus Generalised; Urticaria	Epipen Dayquil				s s	Intramuscular Oral		g, Unk , Qd (1 Dose)		Pfi	zer
	Benadry	vl /00000402/			S		Unk	, (			
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Dec-2017	14310032	EXPEDITED (15-DAY)			ОТ	AU-PFIZER 2017538437				Female	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
Accidental Exposure T Product; Injury Associa Vith Device					S		Unk			Pfi	zer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Dec-2017	14313880	EXPEDITED (15-DAY)			ОТ	AU-MYLANL 2017M1077	_			Female	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>Mfr</u>	
njury Associated With Device; No Adverse Ev	Epipen vent				S					Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Dec-2017	9558287	EXPEDITED (15-DAY)			HO, OT	CA-ROCHE-	1278850		47 YR	Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosag	e Text	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	; Xolair				S	Subcutaneous					
inaphylactic Shock; iphonia; Asthma; Brea	Xolair				S	Subcutaneous					
Pain; Bronchitis; Cellul					S	Subcutaneous					
Cellulitis Streptococcal	; Xolair				S	Subcutaneous					
Contusion; Cough; Decreased Appetite;	Xolair				S	Subcutaneous					
Dizziness; Drug	Xolair				S	Subcutaneous					
neffective; Ecchymosi Eczema; Fatigue; Food					S	Subcutaneous					
Sczema, Fallgue, Foot Allergy; Food Intoleran Generalised Erythema	ce; Xolair				S	Subcutaneous					



Head Injury; Headache;	Xolair	S	Subcutaneous	
Heart Rate Decreased; Hypersensitivity;	Xolair	S	Subcutaneous	1 Ot
Inappropriate Schedule Of	Xolair	S	Subcutaneous	
Drug Administration; Incision Site Pain;	Xolair	S	Subcutaneous	
Injection Site Reaction;	Xolair	S	Subcutaneous	
Insomnia; Mastitis;	Xolair	S	Subcutaneous	
Nasopharyngitis; Nausea; Off Label Use;	Xolair	S	Subcutaneous	
Osteoarthritis; Pain In	Xolair	S	Subcutaneous	
Extremity; Poor Quality Sleep; Pruritus	Xolair	S	Subcutaneous	
Generalised; Pulmonary	Xolair	S	Subcutaneous	
Congestion; Rash Erythematous; Secretion	Xolair	S	Subcutaneous	
Discharge; Self Esteem	Xolair	S	Subcutaneous	
Decreased; Sensation Of Foreign Body; Skin	Xolair	S	Subcutaneous	
Infection; Sneezing;	Xolair	S	Subcutaneous	
Vitamin D Deficiency; Vomiting	Xolair	S	Subcutaneous	
vornung	Xolair	S	Subcutaneous	
	Benadryl (Canada)	S	Unknown	2 Df (50 Mg), Unk
	Benadryl (Canada)	S	Unknown	
	Benadryl (Canada)	S	Unknown	
	Benadryl (Canada)	S	Unknown	
	Reactine (Canada)	S	Unknown	Qhs (At Bed Time)
	Reactine (Canada)	S	Unknown	Qhs (At Bedtime)
	Reactine (Canada)	S	Unknown	Unk
	Epipen	S	Unknown	
	Clavulin	S	Unknown	Unk
	Flovent	С	Unknown	
	Avamys	С	Unknown	



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
22-Dec-2017	14316678	NON-EXPEDITED		(	TC	US-PFIZER 201753783				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Drug Ineffective	Epipen				S	Intramuscular	Unk			Pf	izer
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Dec-2017	14324630	EXPEDITED (15-DAY)		(	TC	AU-MYLAN 2017M1078	-			Male	AUS
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	<u>r</u>
Device Failure; Needle ssue; Product Quality ssue					S		300m	cg/2ml, Unk		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Dec-2017	14325204	EXPEDITED (15-DAY)		[	DE, OT	JP-MYLANI 2017M1079	_			Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Death; Drug Administration Error	Epipen				S		1 Df, S	Single		М	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Dec-2017	14287273	EXPEDITED (15-DAY)		H	HO, OT	AU-PFIZER 201753195				Female	AUS
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Asthma; Reaction To Preservatives	Epipen				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Dec-2017	14330036	NON-EXPEDITED				US-PFIZER 201754843			3 YR	Male	USA
Preferred Term	Produc	ŧ	Comp.	ОТС	Role	Route	Dosage	. Toyt	Duration	Mf	_

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Administration Site Laceration; Administra Site Scar	Epipen tion				S	Unknown	Unk				Unknown
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Dec-2017	14279282	EXPEDITED (15-DAY)			DE	JP-MYLAN 2017M107	_		68 YR	Male	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<b>Duration</b>		<u>Mfr</u>
Death	Epipen				S		Unk				Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Dec-2017	14332117	EXPEDITED (15-DAY)			ОТ	US-PFIZEF 201754607			40 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<b>Duration</b>		<u>Mfr</u>
Device Failure; Device Use Issue; Drug Dose Omission; Dyspnoea; Feeling Abnormal; Paraesthesia Oral; Pharyngeal Oedema; Product Quality Issue	Benadry Epi /001	/I /00000402/ 66003/ ethasone			s c c	Intramuscular	Unk 20 Mg Unk Unk	, Unk			Pfizer
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Dec-2017	14333733	EXPEDITED (15-DAY)			ОТ	US-PFIZEF 201754846			11 YR	Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Accidental Exposure T Product By Child; Erythema; Heart Rate Increased; Hyperhidros	Epipen				s s	Unknown Intramuscular	Unk Unk				Pfizer Pfizer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Dec-2017	14338038	EXPEDITED (15-DAY)			ОТ	JP-PFIZER 201754529	-			Male	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	e Text	<b>Duration</b>	,	<u>Mfr</u>



Accidental Exposure T Product; Injection Site Injury	o Epipen	0.15mg			S					Pi	fizer
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Jan-2018	14240748	EXPEDITED (15-DAY)			HO, LT, OT	GB-MYLAN 2017M1074	-		73 YR	Female	GBR
Preferred Term	Produc	e <u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Issue; Drug Do Omission; Injury Associated With Devic	Injector	(Epinephrine) Auto 0.3 Mg			S	Intramuscular	0.3 Mg	g, Once		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14342368	EXPEDITED (15-DAY)			HO, LT, OT	GB-PFIZER 2017509800			73 YR	Female	GBR
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Device Failure; Device Use Issue; Drug Dose Omission; Injury Associated With Devic Product Quality Issue		0.3mg			S	Intramuscular	0.3 Mg	g, Once		Pi	äzer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
03-Jan-2018	14348110	EXPEDITED (15-DAY)			ОТ	US-PFIZER 2017556058			7 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Accidental Exposure T Product By Child; Peripheral Swelling	o Epipen				S	Intramuscular	Unk			U	nknown
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	14246279	EXPEDITED (15-DAY)			HO, OT	CA-MYLANI 2017M1074			73 YR	Male	CAN
04-Jan-2018	14240270	,				20171011074	439				



Device Failure; Device Use Issue; Drug Dose Omission; Fall; Head Injury; Loss Of Consciousness; Product

Epipen Epipen S Six Times Sicnce 2007
S Unk

Mylan Mylan

Quality Issue

FDA Received Date	Case #	Case Type	<u>Health</u>	<b>Prof</b>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
04-Jan-2018	14353073	EXPEDITED (15-DAY)			LT	US-MYLANLAE 2017M1082670		17 YR	Male	USA
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Device Failure; Drug		Auto-Injector			S		Unk		N	lylan
Ineffective; No Adverse Event	Epipen A	Auto-Injector			S		0.3 Mg, Unk		M	1ylan
LVGIII	Epipen A	Auto-Injector			S				M	1ylan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jan-2018	12934189	EXPEDITED (15-DAY)		(	ОТ	SE-MYLANLAE 2016M1048886			Female	SWE
Preferred Term	Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Wrong Technique In	Epipen				S		Unk		M	lylan
Product Usage Proces	s Zyrlex				С	Oral	Daily Dose: 2 Df Dosage Form Every Days		M	1ylan
	Tavegyl				С		2 Df, Unk		M	1ylan
	Tavegyl Plavix				C C		Unk			1ylan 1ylan
	Plavix Renitec				C C		Unk			1ylan 1ylan
	Plendil				С	Oral	Unk		N	1ylan
	Betapre	d			С		Unk Unk, Prn		M	lylan
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Jan-2018	14147513	NON-EXPEDITED				US-MYLANLAE	3S-	13 YR	Female	USA

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<b>Preferred Term</b>	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	Mf	
Accidental Exposure T Product; Injection Site Pain; Injection Site Swelling; Product Packaging Issue		Auto-Injector			S		Unk		M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Jan-2018	12878279	EXPEDITED (15-DAY)			ОТ	US-PFIZER   2016493949	NC-	12 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mf	
Abdominal Discomfort	; Epiper				S	Intramuscular	0.3 Mg, Prn		Pf	izer
Asthenia; Dyspepsia; Nausea	Solu-M	ledrol			S		Unk		Pf	izer
Nausca	Benad	ryl			S		Unk			
	Pepcid				S		Unk			
	Singula	air			С	Oral	10 Mg, Qam			
	Clarine	ex			С	Oral	5 Mg, Qpm			
	Advair				С	Respiratory (inhalation)	500 Mg, Bid			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jan-2018	14251151	EXPEDITED (15-DAY)			HO, LT, OT	US-PFIZER   2015373253	NC-	16 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>	Mf	[
Clostridial Infection; G	as Epiper				S	Intramuscular	0.3 Mg, Single		Pf	izer
Gangrene; Infective Myositis; Injection Site	Epiper				S		0.3 Mg, Unk		Pf	izer
Pain; Necrotising Fasc Necrotising Myositis; Oedema Peripheral; Product Contaminatior Microbial; Septic Shoc Walking Disability	ciitis; Epiper Epiper n				S S		<b>3</b> , 3			izer izer



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jan-2018	14348185	EXPEDITED (15-DAY)			ОТ	US-PFIZER IN 2017549550	NC-	13 YR	Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Device Failure; Device Use Issue; Expired Product Administered; Heart Rate Decreased Incorrect Dose Administered; Needle Issue	Epipen				S S	Intramuscular Intramuscular	1 Df, Unk 1 Df, Unk			Pfizer Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jan-2018	11692755	EXPEDITED (15-DAY)			HO, LT, OT	US-MYLANLA 2015M103823		16 YR	Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<b>Duration</b>		<u>Mfr</u>
Clostridial Infection; G Gangrene; Infective Myositis; Injection Site Pain; Necrotising Fasc Necrotising Myositis; Oedema Peripheral; Product Contamination Microbial; Septic Shoot Walking Disability	Epipen Siitis; Epipen Epipen	Auto-Injector Auto-Injector Auto-Injector Auto-Injector			s s s	Intramuscular Intramuscular	Unk Unk, Once 0.3 Mg, Unk			Mylan Mylan Mylan Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jan-2018	14306009	NON-EXPEDITED				US-PFIZER IN 2017534677	NC-	11 YR	Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Accidental Exposure T Product By Child; Erythema; Foreign Bo Heart Rate Increased; Hyperhidrosis	dy;				S		Unk			Pfizer



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jan-2018	14370488	NON-EXPEDITED				US-PFIZER 2018006897	-			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mfr	<u>.</u>
Pruritus	Epipen				S		Unk			Pfi	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jan-2018	14334663	EXPEDITED (15-DAY)			ОТ	GB-MYLAN 2017M1079			27 YR	Female	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>je Text</u>	<b>Duration</b>	Mfr	!
Accidental Exposure To Product; Nervousness; Pain In Extremity	o Epipen				S		Unk			Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Jan-2018	14375660	EXPEDITED (15-DAY)			ОТ	US-MYLANI 2017M1083	-		23 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mfr	
Device Failure; No Adverse Event	Metopro	Auto-Injector Iol I /00139501/			S C C	Intramuscular	3 Mg, 100 N	, Unk Иg, Unk		Му	/lan /lan /lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jan-2018	14159539	NON-EXPEDITED				US-PFIZER 2017471176	-		13 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>	Mfr	
Accidental Exposure To Product; Injection Site Pain; Injection Site Swelling; Product Packaging Issue	o Epipen				S		Unk			Pfi	izer



FDA Received Date Ca	<u>se #</u>	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
15-Jan-2018 112	267404	EXPEDITED (15-DAY)			DE, HO	US-MYLANLAE 2015M1022308	=	58 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Anaphylactic Reaction;	Epipen	Auto-Injector			S	Intramuscular	0.3 Mg, Unk			Mylan
Anaphylactic Shock; Blindness; Cardiac Arrest;	Ceftriax	one Sandoz			S	Intramuscular	1 G, Once, Left Buttock			Mylan
Condition Aggravated; Injection Site Pruritus;	Depo-N	<b>l</b> edrol			S	Intramuscular	100 Mg, Once, Right Buttock			Mylan
Loss Of Consciousness; Pruritus; Rash Generalised; Sinusitis;	Lidocai	ne			S	Intramuscular	Unk, Dilute With Ceftriaxone, In Left Buttock			Mylan
Unresponsive To Stimuli	Lidocai Cyanod	ne cobalamin			S S	Intramuscular	1000 Mg, Once For A While Into Left Shoulder			Mylan Mylan
	Cyanoo	cobalamin			S	Unknown	Unk Mg, Unk			Mylan
	Cyanoo	cobalamin			S	Unknown	1000 Mg, Unk			Mylan
	Vitamin	B12 /00056201/			S	Intramuscular	Unk			Mylan
FDA Received Date Ca	se #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jan-2018 143	303185	EXPEDITED (15-DAY)			ОТ	CA-PFIZER IN0 2017538436	C-	5 YR	Male	CAN
Preferred Term	Produc	<u>et</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Complication Of Device	Epipen	Jr			S		Unk			Pfizer
Removal; Device Issue; Drug Ineffective; Injection Site Discolouration; Injection Site Injury; Injection Site Pain; Injury Associated With Device; Needle Issue; Product	Epipen Benadr				S C		Unk			Pfizer



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jan-2018	14403325	EXPEDITED (15-DAY)		ŀ	НО	JP-MYLANI 2018M1004	_			Male	JPN
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage 1	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Hospitalisation	Е	pipen			S					М	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jan-2018	14403666	NON-EXPEDITED				US-MYLAN 2018M1002				Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Text</u>	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Device Failure	Е	pipen Auto-Injector			S	Subcutaneous	Unk			M	lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jan-2018	14333815	EXPEDITED (15-DAY)		ŀ	HO, OT	CA-PFIZER 2017544567			15 YR	Male	CAN
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Drug Ineffective; Vomit	ting E	pipen			S		Unk			U	nknown
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jan-2018	14371898	B EXPEDITED (15-DAY)		[	DE, HO, OT	US-PFIZER 2899860	INC-		58 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTC	Role	Route	Dosage 1	<u>Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Anaphylactic Reaction	; E	pipen			S	Intramuscular	0.3 Mg,	Unk		P	fizer
Anaphylactic Shock; Cardiac Arrest; Conditi	ion D	epo Medrol			S	Intramuscular	100 Mg,	Single		P	fizer
Aggravated; Injection S	Site Li	docaine Hcl			S	Intramuscular	Unk, Sin	gle		U	nknown
Indentation; Injection S Pruritus; Loss Of	<sup>Site</sup> C	eftriaxone Sodium			S	Intramuscular	1 G, Sin	gle		P	fizer
Consciousness; Pruritu Rash Generalised; Sinusitis; Sudden Visu Loss; Unresponsive To Stimuli	al	itamin B12			S	Intramuscular	1000 Ug	l, Once, For A nto Left Shoulder			



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jan-2018	14406593	EXPEDITED (15-DAY)			НО	-	ANLABS- 1004616			Female	JPN
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	!
Hospitalisation	Epipen				S		Unk			M	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jan-2018	14407289	EXPEDITED (15-DAY)		1	ОТ	CA-PFI 201801	ZER INC- 7819		51 YR	Female	CAN
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	[
Condition Aggravated; Nausea; Sinus Tachycardia; Throat Tightness; Vomiting	Epipen				S		Unk			Pf	izer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14417939	DIRECT			но, от				40 YR	Male	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>Mf</u>	<u>:</u>
Injection Site Abscess	Epipen				S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14419789	EXPEDITED (15-DAY)			но, от	US-PFI 201802	ZER INC- 6144		26 YR	Male	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mf</u>	!
Anaphylactic Shock;	Epipen				S		Unk			Pf	izer
Device Failure; Device Use Issue; Erythema; Expired Product Administered; Feeling Abnormal; Injection Sit Haemorrhage; Injury Associated With Devic Needle Issue; Pain In	е				S		Unk			Pf	izer

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Extremity; Skin Injury;

<b>FDA Received Date</b>	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cor	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
22-Jan-2018	14420169	EXPEDITED (15-DAY)		ŀ	HO, OT	US-MYL 2018M10	ANLABS- 004450		26 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Anaphylactic Shock; Device Failure; Erythe Expired Product Administered; Feeling Abnormal; Injection Si Haemorrhage; Injury Associated With Devic Pain In Extremity; Skir Injury; Swelling Face	ema; Epiper ite ce;	n Auto-Injector n Auto-Injector			S S						ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jan-2018	14413191	EXPEDITED (15-DAY)		[	DE, HO, OT	US-PFIZ 2018025			18 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Brain Injury; Cardiac Arrest; Consciousness Fluctuating; Dyspnoea Expired Product Administered					S		Unk			Pf	äzer
FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jan-2018	14441982	EXPEDITED (15-DAY)		l	LT, OT	CA-MYL 2018M10	ANLABS- 005519			Female	CAN
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Device Failure; Produc Quality Issue	ct Epiper	1			S	Intramuscular				М	ylan

Note: If the field is blank, there is no data.

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FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jan-2018	14452637	EXPEDITED (15-DAY)			DE, OT	PHEH2018US	002429	58 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Anaphylactic Shock;		kone Sandoz			S	Intramuscular	1 G, Once/Single, Left Buttock		No	vartis
Blindness; Cardiac Arro Condition Aggravated; Injection Site Pruritus; Loss Of Consciousness	Lidocai	ne			S	Intramuscular	Unk, Dilute With Ceftriaxone, In Left Buttock			
Pruritus; Rash	Lidocai				S					
Generalised; Sinusitis;					S	Intramuscular	0.3 Mg, Qd			
Unresponsive To Stimu	الد Depo-N	<b>1</b> edrol			S	Intramuscular	100 Mg, Once, Right Buttock			
	Vitamin	B12			S	Intramuscular	1000 Ug, Once, For A While Into Left Shoulder			
	Vitamin	B12			S	Unknown	1000 Ug, Unk			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Jan-2018	14454667	NON-EXPEDITED				US-MYLANLA 2018M100733			Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; No	Epipen	Auto-Injector			S	Intramuscular			My	rlan
Adverse Event	Epipen	Auto-Injector			S	Intramuscular			Му	/lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jan-2018	14432662	EXPEDITED (15-DAY)			DE, OT	CA-PFIZER IN 2018029752	C-		Male	CAN
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Death; Expired Product Administered	t Epipen				S		Unk		Pfi	zer



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health	Prof (	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2018	13393153	EXPEDITED (15-DAY)		[	DE, OT	AU-PFIZER 2017134714			79 YR	Male	AUS
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Anaphylactic Reaction	; Epipen				S		2 Df, l	Jnk			Pfizer
Myocardial Infarction; Product Use Issue	Epipen				S		2 Df, l	Jnk			Pfizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2018	14312717	EXPEDITED (15-DAY)		l	T, OT	US-MYLAN 2017M1079			40 YR	Female	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>		<u>Mfr</u>
Device Failure; Drug D	Dose Epipen	Auto-Injector			S	Intramuscular	Unk				Mylan
Omission	Benadr	yl /00000402/			С		20 Mg	ı, Unk			Mylan
	Epi /00	166003/			С		Unk				Mylan
	Dexam	ethasone			С						Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Dutcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2018	14469734	EXPEDITED (15-DAY)		l	T, OT	CA-MYLAN 2018M1005	-			Female	CAN
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>		<u>Mfr</u>
Device Failure; No Adverse Event; Produc Quality Issue	Epipen ct				S	Intramuscular	Unk				Mylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2018	14472270	EXPEDITED (15-DAY)		(	DΤ	US-MYLAN 2018M1005	_			Male	USA
Preferred Term	Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<b>Duration</b>		<u>Mfr</u>
Device Failure	Epipen	Auto-Injector			S	Intramuscular	1 Df, l	Jnk			Mylan
		Auto-Injector			S		Unk				Mylan



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr C	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14431618	EXPEDITED (15-DAY)			ОТ	_	YLANLABS- M1005158		12 YR	Female	AUS
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; No Adverse Event	Epipen				S		Unk			Му	rlan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr C	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14473755	NON-EXPEDITED					FIZER INC- )40499			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Expired Produ Administered; Injection Site Hypoaesthesia	uct				S					Un	known
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr C	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Feb-2018	12860821	EXPEDITED (15-DAY)			HO, LT, OT	PHHY	′2016AU140855			Female	AUS
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Tryptase Increased	; Loratadi Ranitidir Interferc Epipen				\$ \$ \$ \$	Unknown Unknown Unknown Unknown	Unk			No	vartis
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr C	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Feb-2018	14478857	NON-EXPEDITED					FIZER INC- 044765			Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure T Product; Injection Site Haemorrhage	o Epipen				S	Unknown	Unk			Pfi	zer

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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Feb-2018	14478998	NON-EXPEDITED				US-PFIZE 20180447				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mf</u>	<u>'r</u>
Contusion; Injury Associated With Devic Pain	Epipen e;	Jr			S		Unk			Pi	fizer
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Feb-2018	14485007	NON-EXPEDITED				US-PFIZE 20180469				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>ir</u>
Accidental Exposure T Product; Expired Product; Administered; Injection Site Hypoaesthesia	uct				S	Unknown	Unk			U	nknown
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Feb-2018	14485903	EXPEDITED (15-DAY)		(	TC	JP-MYLAN 2018M100				Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mf</u>	<u>ir</u>
Accidental Underdose; Device Failure; Device Use Issue; Needle Issu	Fninen	ie.			s s c		0.15 M			М	ylan Iylan ylan
Pallor; Product Quality Issue	Alvesco				С	Oral Endotracheal	5 Mg, 100 M				ylan
FDA Received Date	Case #	Case Type	Health	Prof (	<u>Outcomes</u>	Mfr Cont	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Feb-2018	14488159	NON-EXPEDITED				US-MYLA 2018M100				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>'r</u>
No Adverse Event;	Epipen				S	Intramuscular	0.3 Mg	g, Prn		М	ylan
Product Use In	Epipen				S					М	ylan

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Unapproved Indication	1										
<b>FDA Received Date</b>	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2018	14419963	EXPEDITED (15-DAY)			HO, OT	US-MYLANI 2018M1004	_		29 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage <sup>-</sup>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure	Epip	en Auto-Injector			S	Subcutaneous	0.3 Mg,	Unk		Му	lan
	Epip	en Auto-Injector			S	Subcutaneous	Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14078893	NON-EXPEDITED				US-MYLANI 2017M1025	_		17 YR	Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage <sup>-</sup>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dose Omission; Intentional Product Misuse; Product Color Issue		en Auto-Injector			S		Unk			Му	lan
<b>FDA Received Date</b>	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14080220	NON-EXPEDITED				US-MYLANI 2017M1032	_			Unknown	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage 7	<u>Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Drug Domission		oen Auto-Injector oen Auto-Injector			s s	Intramuscular	0.3 Mg,	Prn		-	lan lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14080675	NON-EXPEDITED				US-MYLANI 2017M1039	-			Female	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage T	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Drug Domission	Dose Epip	en Auto-Injector			S		Unk			Му	lan



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(							-				
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Outcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14081695	NON-EXPEDITED				US-MYLAN 2017M1043			70 YR	Female	USA
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Device Failure; Drug D Omission	Dose Epipe	n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14082095	NON-EXPEDITED				US-MYLAN 2017M1047	-		22 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mf	<u>r</u>
Device Failure; Drug D Omission		n Auto-Injector n Auto-Injector			S S	Intramuscular	0.3 Mg	g, Prn		•	ylan ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14121280	NON-EXPEDITED				US-MYLAN 2017M1056			16 YR	Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>.</u>
Device Failure; Drug D Omission; Injection Sit Haemorrhage		n Auto-Injector			S	Intramuscular	0.3 Mg	g, Prn		My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14213797	NON-EXPEDITED				US-MYLAN 2017M1072				Male	USA
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mf	<u>r</u>
Device Failure; Drug D Omission	Dose Epipe	n Auto-Injector			S		0.3 Mg	g, Prn		My	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Dutcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14293062	NON-EXPEDITED				US-MYLAN 2017M1078				Female	USA



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Need Issue	lle Epipen	Auto-Injector			S	Intramuscular	Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2018	14542528	EXPEDITED (15-DAY)			ОТ	CA-MYLANL 2018M10120	-		28 YR	Male	CAN
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mfr	
Device Failure; No Adverse Event; Produ Quality Issue	Epipen ct				S		Unk			Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Feb-2018	14553583	EXPEDITED (15-DAY)			ОТ	CA-MYLANL 2018M10096	-			Female	CAN
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	<u>Mfr</u>	
Device Failure; Device Use Issue; Liquid Prod Physical Issue; Needle	duct	Jr.			S	Intramuscular	Unk			Му	lan
	ent	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Issue; No Adverse Eve	ent	Case Type EXPEDITED (15-DAY)	Health		Outcomes LT, OT	Mfr Contro CA-MYLANL 2018M10116	ABS-	503B Facility	Age	<u>Sex</u> Female	Country CAN
Issue; No Adverse Eve FDA Received Date 20-Feb-2018	ent Case #	EXPEDITED (15-DAY)	Health Comp.		LT, OT	CA-MYLANL	ABS-	•	Age  Duration		CAN
FDA Received Date 20-Feb-2018  Preferred Term  Device Failure; Produce	Case # 14554977 Produc	EXPEDITED (15-DAY)			LT, OT	CA-MYLANL 2018M10116	_ABS- 607	•	_	Female	CAN
FDA Received Date 20-Feb-2018  Preferred Term  Device Failure; Produce	Case #  14554977  Product Epipen	EXPEDITED (15-DAY)	Comp.	отс	LT, OT	CA-MYLANL 2018M10116 Route	LABS- 607 <b>Dosage</b> Unk	•	_	Female	CAN
Issue; No Adverse Eve FDA Received Date 20-Feb-2018 Preferred Term Device Failure; Produc Quality Issue	Case #  14554977  Product Epipen	EXPEDITED (15-DAY)	Comp.	OTC Prof	LT, OT  Role S	CA-MYLANL 2018M10116 Route Intramuscular	Dosage Unk  Di#  ABS-	e Text	<u>Duration</u>	Female <u>Mfr</u> My	CAN
FDA Received Date 20-Feb-2018  Preferred Term  Device Failure; Productive Quality Issue  FDA Received Date	Case #  14554977  Product Epipen  Case #	EXPEDITED (15-DAY)  Case Type  EXPEDITED (15-DAY)	Comp.	OTC Prof	Role S Outcomes DE	CA-MYLANL 2018M10116  Route  Intramuscular  Mfr Contro	Dosage Unk  Di#  ABS-	503B Facility	<u>Duration</u>	Female  Mfr  My  Sex	CAN lan Country



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>He</u>	alth I	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Feb-2018	145679	92 EXPEDITED (	15-DAY)		0	Γ	NO-MYLANI 2018M1012	_		9 YR	Female	NOR
Preferred Term		Product	Con	<u>ıp.</u>	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Adverse Reaction; Experior Product Administered; Headache; Increased Upper Airway Secretic Nausea	,	Epipen Jr				S		Unk, <sup>-</sup>	Γotal		Μ	1ylan
FDA Received Date	Case #	Case Type	<u>He</u>	alth I	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Feb-2018	· ·		15-DAY)		0	Γ	US-MYLANI 2018M1012				Female	USA
Preferred Term		Product	Con	<u>ıp.</u>	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
	rug Ineffective; Incorrect					S	Subcutaneous	Unk			M	lylan
Route Of Drug Administration		Epinephrine				S	Subcutaneous	Unk				
		Allegra Benadryl /00000402/ Valaciclovir Losartan Buspirone				C C C C					N N N	1ylan 1ylan 1ylan 1ylan 1ylan
FDA Received Date	Case #	Case Type	<u>He</u>	alth I	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Feb-2018	141374	EXPEDITED (	15-DAY)		Н	O, OT	CA-MYLANI 2017M1067			51 YR	Female	CAN
Preferred Term		Product	Con	<u>ıp.</u>	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Compartment Syndror	me;	Epipen				S	Intramuscular	0.3 M	g, Unk		N	lylan
Device Failure; Gait Disturbance; Injection	Site	Epipen				S	Intramuscular		g, Unk		M	lylan
Pain; Limb Injury; Mus		Epipen				S	Intramuscular	0.3 M	g, Unk		M	1ylan
utrophy; Muscular Veakness; Oedema; Pa n Extremity; Scar;	Pain	Thrive /01033302/ Nicoderm				C C		21mg	/24h			1ylan 1ylan
Sensory Disturbance; Walking Aid User		Pms-Valacyclovir Ventolin Hfa				C C		100 M	lg, 2 Inhalations			1ylan 1ylan



		Dotanoa No	P • · ·	
Teva Alendronate/Cholecalciferol	С		Unk	Mylan
D-Tabs	С		1000ui	Mylan
Alprazolam	С		0.5 Mg, Unk	Mylan
Dilaudid	С	Oral	2 Mg, Pm	Mylan
Dilaudid	С	Subcutaneous	2 Mg, Pm	Mylan
Dilaudid	С	Subcutaneous	2 Mg, Pm	Mylan
Dilaudid	С	Subcutaneous	2 Mg, Am	Mylan
Dilaudid	С	Subcutaneous	2 Mg, Every 3 Hr As Needed	Mylan
Dilaudid	С	Subcutaneous	4 Mg, Every 3 Hr As Needed	Mylan
Dilaudid	С	Subcutaneous	2 Mg, Unk	Mylan
Dilaudid	С	Subcutaneous	2 Mg, Q4h As Needed	Mylan
Dilaudid	С	Subcutaneous	2 Mg, Q3n As Needed	Mylan
Dilaudid	С	Oral	4 Mg, Q3h As Needed	Mylan
Dilaudid	С	Oral	1 Mg, Unk	Mylan
Esomeprazole	С		Unk	Mylan
Diltiazem Hcl Teva	С		180 Mg, Qd	Mylan
Rosuvastatin	С		10 Mg, Qd	Mylan
Mometasone	С		50 Mg, 2 Inhalations	Mylan
Cal-500	С		500 Mg, Bid	Mylan
Fentanyl Matrix	С		75 Mg, Per Hr	Mylan
Benadryl	С	Intravenous (not otherwise specified)	50 Mg, Unk	Mylan
Benadryl	С		Unk	Mylan
Zantic	С	Intravenous (not otherwise specified)	50 Mg, Unk	Mylan
Solu-Medrol	С	Intravenous (not otherwise specified)	125 Mg, Unk	Mylan
Nacl	С		Unk	Mylan



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	<u>ŧ</u>	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Feb-2018	145739	910	EXPEDITED (15-DAY)		ŀ	HO, OT	CA-MYLANLA 2018M101340	_		14 YR	Female	CAN
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mf	<u>.</u>
Device Ineffective; Intentional Product Use Issue	е	Epipen Epipen				S S	Intramuscular Intramuscular	Unk			,	ylan ylan
FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof (	<u>Dutcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Feb-2018	141285	538	EXPEDITED (15-DAY)		ŀ	HO, OT	CA-PFIZER IN 2017454302	IC-		51 YR	Female	CAN
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	Mf	_
Compartment Syndron Device Failure; Device Use Issue; Gait Disturbance; Injection Pain; Muscle Atrophy; Muscular Weakness; Oedema; Product Qua Issue; Scar; Sensory Disturbance	Site	Nicoder Pms-Va Ventolir Alendro W/Coler D-Tabs Alprazo Dilaudio Apo Eso Diltiazer Pms Ro	alacyclovir  a Hfa nate Sodium calciferol  lam d omeprazole m Hcl Teva esuvastatin metasone			s	Intramuscular	100 Ug 70 Mg 1000 I 0.5 Mg 2 Mg, 40 Mg	Unk , Unk g, Unk g, Unk , Unk u, Unk g, Unk Unk , Unk , Unk , Unk g, Unk		Pf	izer
FDA Received Date 28-Feb-2018	Case #	_	Case Type  NON-EXPEDITED	<u>Health</u>	Prof (	<u>Outcomes</u>	Mfr Control US-MYLANLA 2017M107873	BS-	503B Facility	Age	<u>Sex</u> Female	<u>Country</u> USA



Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Drug Ineffective	Epiper	n Auto-Injector			S	Intramuscular	0.3 Unk, Unk		M	1ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contr	ol # 503B Facili	ty <u>Age</u>	<u>Sex</u>	Country
01-Mar-2018	14588152	EXPEDITED (15-DAY)		C	Т	US-MYLAN 2018M1013			Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Drug Ineffective; Produ Supply Issue	uct Epiper	า			S	Intramuscular			Ν	1ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contr	ol # 503B Facili	ty <u>Age</u>	<u>Sex</u>	Country
06-Mar-2018	14309156	EXPEDITED (15-DAY)		C	T	CA-MYLAN 2017M1077	_	5 YR	Male	CAN
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Complication Of Device Removal; Device Issue Drug Ineffective; Inject Site Discolouration; Injection Site Injury; Injection Site Pain; Inju Associated With Device Needle Issue; Product Quality Issue	e; Epiper tion Benad ury	n Jr			S S C		Unk Unk		M	1ylan 1ylan 1ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>utcomes</u>	Mfr Contr	ol # 503B Facili	<u>ty</u> <u>Age</u>	<u>Sex</u>	Country
06-Mar-2018	14322387	NON-EXPEDITED				US-MYLAN 2017M1079	_	13 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<b>Duration</b>	<u>M</u> :	<u>fr</u>
Device Failure; Expire		ohrine Injection Usp Auto-			S	Intramuscular	1 Df, Unk		M	lylan
Product Administered; Heart Rate Decreased Needle Issue		n Auto-Injector			S	Intramuscular	1 Df, Unk		M	<b>1</b> ylan



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

						201404 .	торо: -				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Mar-2018	14613332	EXPEDITED (15-DAY)		07	Γ	CA-MYLANI 2018M1006				Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure; Device Use Issue; Needle Issu No Adverse Event;					s s	Intramuscular Intramuscular	Unk Unk				/lylan /lylan
Product Quality Issue	Epipen				S	Intramuscular	Unk			N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
09-Mar-2018	14596018	NON-EXPEDITED				US-MYLANI 2018M1013				Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<b>Duration</b>	<u>M</u>	<u>fr</u>
Accidental Exposure T Product; Adverse Ever Injury Associated With Device	nt;	Auto-Injector			S		Unk			N	<b>/</b> lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
12-Mar-2018	14627121	EXPEDITED (15-DAY)		DE	<b>=</b>	JP-MYLANL 2018M1015	_			Unknown	JPN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Death	Epipen				S	Intramuscular				N	/lylan
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Mar-2018	14291160	EXPEDITED (15-DAY)		Н	O, OT	PT-MYLANL 2017M1077			22 YR	Male	PRT
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	e Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Device Failure; No	Epipen				S	Intramuscular	Unk			N	/lylan
Adverse Event; Produc Quality Issue	ct Lepicor	tinolo /00016201/			С	Oral	Unk			N	/lylan
	Zyrtec /	00884302/			С	Oral	Unk			N	Nylan
	Adrenal	ine /00003901/			С					N	/lylan



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Mar-2018	14080646	NON-EXPEDITED				US-MYLAN 2017M1039	-			Female	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<b>Duration</b>	Mfr	
Accidental Exposure T Product; Device Issue Headache; Lethargy; Nausea; Vomiting		n Auto-Injector			S	Subcutaneous	Unk			Му	vlan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Mar-2018	14647109	EXPEDITED (15-DAY)			НО	NZ-MYLAN 2018M1017	-		75 YR	Female	NZL
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<u>Duration</u>	Mfr	
Drug Ineffective; No Adverse Event	Epipe	n			S		Unk, Requ	Prn (Use When ired)		My	/lan
	Cilaza	april			С	Oral	Unk	·		My	/lan
	Plend	il			С	Oral	Unk			My	/lan
	Celol	/00514701/			С	Oral	Unk			My	/lan
	Lactu	lose			С	Oral	Unk			My	/lan
	Losed	00661201/			С	Oral	Unk			My	/lan
	Lipex	/00848101/			С	Oral	Unk			My	<i>r</i> lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Mar-2018	14292801	NON-EXPEDITED				US-MYLAN 2017M1078			9 YR	Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mfr	
Device Defective; Injur Associated With Device		n Auto-Injector			S	Subcutaneous	Unk l	Jnk, Prn		My	/lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Mar-2018	14673190	EXPEDITED (15-DAY)			ОТ	AU-MYLAN 2018M1018				Male	AUS



Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Device Failure; No Adverse Event	Epipen Epipen				S S					My My	
FDA Received Date	Case #	Case Type	Health	Prof C	<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Mar-2018	14684702	DIRECT	Υ						26 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Device Malfunction; Drug Ineffective	Epipen e				S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Mar-2018	14690789	EXPEDITED (15-DAY)		C	TC		_ANLABS- 020878			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma	Epipen /	Auto-Injector			S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Mar-2018	14667509	EXPEDITED (15-DAY)		L	T, OT	GB-MY 2018M1	_ANLABS- 018440		52 YR	Female	GBR
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
Device Issue; No Adve		Adrenaline Auto			S		Unk, C	nce		Му	lan
Event		Adrenaline Auto			S					Му	lan
	Injector Salbutai				С		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Mar-2018	14694163	EXPEDITED (15-DAY)		C	T		_ANLABS- 018271		52 YR	Female	USA
Preferred Term	Produc	•	Comp.	ОТС	Role	Route	Dosage	Toyt	Duration	Mfr	

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#### **FDA Adverse Event Reporting System** Freedom of Information Act (FOIA) **Detailed Report**

Device Failure; Drug Ineffective: Injection Site Epipen Auto-Injector

S

Unk

Mylan

<b>FDA Received Date</b>	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B F	Facility -	<u>Age</u>	<u>Sex</u>	Country
29-Mar-2018	14695886	DIRECT	Υ	R	I, OT				4 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text		<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction Laceration; Needle Iss		n Jr., 0.15mg/0.3ml Mg			S						
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol # 503B F	Facility	<u>Age</u>	<u>Sex</u>	Country
30-Mar-2018	14699570	EXPEDITED (15-DAY)		Lī	Г, ОТ	CA-MYLAN 2018M1018			43 YR	Female	CAN
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	<b>Dosage Text</b>		<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction Device Issue; Device Malfunction; General Symptom; Loss Of Consciousness	ı; Epipeı	n			S	Intramuscular	0.3 Mg, Once			Му	rlan
001100100011000											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Contro	ol # 503B F	Facility Pacific Property 1981	<u>Age</u>	<u>Sex</u>	Country
	Case # 14699572	Case Type EXPEDITED (15-DAY)	<u>Health</u>	Prof O		Mfr Contro CA-MYLAN 2018M1018	LABS-	Facility	Age 30 YR	<u>Sex</u> Female	<u>Country</u> CAN
FDA Received Date		EXPEDITED (15-DAY)	Health  Comp.			CA-MYLAN	LABS-	<u>Facility</u>			CAN
FDA Received Date 30-Mar-2018  Preferred Term  Abortion Spontaneous Maternal Exposure Du	14699572  Products; Epiper	EXPEDITED (15-DAY)		0	Т	CA-MYLAN 2018M1018	LABS- 750	Facility	30 YR	Female Mfr	CAN
FDA Received Date 30-Mar-2018  Preferred Term  Abortion Spontaneous Maternal Exposure Du	14699572  Production: Epiper Production:	EXPEDITED (15-DAY)  ict  n® Jr. Adrenaline Auto	Comp.	OTC	T Role	CA-MYLAN 2018M1018 Route	Dosage Text  0.3 Mg, Unk	Facility Facility	30 YR	Female Mfr	CAN
FDA Received Date 30-Mar-2018  Preferred Term  Abortion Spontaneous Maternal Exposure Du Pregnancy	14699572  Production: Epiper Production:	EXPEDITED (15-DAY)  ICt  n® Jr. Adrenaline Auto  or 0.15mg	Comp.	OTC	Role S	CA-MYLAN 2018M1018 Route Intramuscular	Dosage Text  0.3 Mg, Unk  ol # 503B F	•	30 YR <u>Duration</u>	Female <u>Mfr</u> My	CAN dan



Device Issue; Needle ssue; No Adverse Eve	Epipen ent				S	Intramuscular	0.3 M	g, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
02-Apr-2018	14706669	EXPEDITED (15-DAY)			LT	GB-MYLANI 2018M10217				Female	GBR
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Device Issue; Needle ssue; No Adverse Eve	Epipen ent				S	Intramuscular	300 N	lg, Prn		Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
03-Apr-2018	14321240	EXPEDITED (15-DAY)			ОТ	JP-MYLANL 2017M10796	-		39 YR	Female	JPN
Preferred Term	Product	<u>I</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
Device Failure; Device	Epipen				S		Unk			Му	lan
Jse Issue; Drug Dose Omission; No Adverse Event; Product Quality ssue					S		Unk			Му	lan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Apr-2018	14516163	EXPEDITED (15-DAY)			ОТ	CA-MYLANI 2018M1010	-		4 YR	Female	CAN
Preferred Term	Product	<u>t</u>	Comp.	OTC	Role	<u>Route</u>	Dosage	e Text	<b>Duration</b>	<u>Mfr</u>	
Anaphylactic Reaction; Device Failure; Device Jse Issue; Drug Dose Dmission; Needle Issue Product Quality Issue		Jr			S					Му	lan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Apr-2018	14632684	NON-EXPEDITED				US-MYLANI 2018M10172	_			Female	USA



Feeling Abnormal; Injection Site Pain; Ned Issue; Palpitations; Tre					S	Intramuscular	Unk				Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	Sex	Country
09-Apr-2018	14692879	EXPEDITED (15-DAY)			HO, LT	FI-MYLANLAB 2018M102000			31 YR	Female	FIN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated;	Epipen				S		300 M	g, Unk			Mylan
Device Failure; Wrong Technique In Product	Epipen				S		300 M	g, Unk			Mylan
Usage Process	Epipen Epipen Epipen Epipen				\$ \$ \$ \$						Mylan Mylan Mylan Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control a	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Apr-2018	14735321	EXPEDITED (15-DAY)			ОТ	US-OTSUKA- 2018_008053			15 YR	Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>		<u>Mfr</u>
Anxiety; Condition	Onzetra	Xsail			S	Nasal	11 Mg	In Each Nostril			Avanir
Aggravated; Drug Administered To Patiei	Epipen				S	Unknown	Unk				
Of Inappropriate Age;	Zoloft				С	Unknown	Unk				
Fatigue; Hypersensitivi	ity; Fluticaso	one			С	Unknown	Unk				
Hypopnoea; Muscle Tightness	Fluticaso	one			С						
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2018	14700217	EXPEDITED (15-DAY)			DE, OT	GB-MYLANLAI 2018M1021780			11 YR	Male	GBR
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	Text	<b>Duration</b>		<u>Mfr</u>
Anaphylactic Shock; Device Failure	Epipen				S		Unk				Mylan



## FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

							<u>-</u>				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Apr-2018	14759854	NON-EXPEDITED				US-MYLAN 2018M101	_		36 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTC	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Injection Site Hypoaesthesia; Injectic Site Pain; Prescription Drug Used Without A Prescription		n Auto-Injector			S	Unknown	Unk			M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
13-Apr-2018	14759855	NON-EXPEDITED				US-MYLAN 2018M101				Female	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Palpitations	Epipei	n Jr. Auto-Injector			S	Intramuscular	Unk			М	ylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Apr-2018	13371043	EXPEDITED (15-DAY)			DE, OT	AU-MYLAN 2017M101	_		79 YR	Male	AUS
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<b>Duration</b>	Mf	<u>r</u>
Anaphylactic Reaction; Myocardial Infarction; Product Use Issue		n (Epinephrine) Auto or 0.3 Mg			S		2 Df,	Unk		М	ylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2018	14494152	NON-EXPEDITED				US-MYLAN 2018M100	_			Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosag	e Text	<b>Duration</b>	<u>Mf</u>	<u>r</u>
Device Failure	Epipei	n Auto-Injector			S					M	ylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2018	14708814	NON-EXPEDITED				US-MYLAN 2018M102	_		49 YR	Female	USA



Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Contusion; Impaired Healing; Injection Site Injury; Injection Site Pa Needle Issue; Pain		Auto-Injector			S	Intramuscular	Unk			N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2018	14769826	EXPEDITED (15-DAY)			ОТ	AU-MYLAN 2018M1023				Male	AUS
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Drug Ineffective	Epipen	1			S		Unk			N	Mylan
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Apr-2018	14770446	NON-EXPEDITED				US-MYLAN 2018M1021			49 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<b>Duration</b>	<u>M</u>	<u>lfr</u>
Accidental Exposure To Product; Device Break Feeling Jittery		Auto-Injector			S	Intramuscular	Unk			N	Mylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2018	14734335	EXPEDITED (15-DAY)			ОТ	AU-MYLAN 2018M1021				Male	AUS
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Device Failure; No Adverse Event	Epipen	1			S		Unk			N	Mylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2018	14773290	NON-EXPEDITED				US-MYLAN 2018M1022	_			Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Device Difficult To Use Device Failure; Produc	, i i	Auto-Injector			S	Unknown	Unk			N	Mylan

Date - Time: 15-May-2018 01:32:07 PM EST Note: If the field is blank, there is no data.



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<b>Country</b>
18-Apr-2018	14774443	EXPEDITED (15-DAY)		0	т	US-MYLAN 2018M1024				Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Malfunction; Drug Epipen Jr. Auto-Injector Dose Omission; Needle Issue				S	Intramuscular	0.3 MI,	Unk		N	⁄lylan	
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2018	14774552	EXPEDITED (15-DAY)		0	Т	IE-MYLANL 2018M1013				Female	IRL
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Drug Ineffective; No Adverse Event	Epipen		S Intramuscular 300 Mg, Unk				Mylan				
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Apr-2018	14775758	NON-EXPEDITED				US-MYLAN 2018M1023			Unknown USA		
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Device Failure	Epipen	Auto-Injector			S		Unk			N	/lylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Apr-2018	13535849	EXPEDITED (15-DAY)		Н	0	CA-APOTEX- 2017AP011461			52 YR	Male	CAN
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	Text	<b>Duration</b>	<u>M</u>	<u>fr</u>
Hypersensitivity	Amlodi	pine			S	Oral	10 Mg,	Qd		A	potex
	Moxiflo	oxacin			S	Ophthalmic	Unk, Q	ıd		A	potex
	Besiva				S	Unknown	Unk, T	id			
	Betopti	ic S			S	Unknown	Unk, Q	d			
	Cialis				S	Unknown	2 Df, C	)d			

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	Cialis	3			S	Unknown	Unk, Bid			
	Cialis	5			S	Ophthalmic	Unk			
	Epipe	en			S	Intramuscular	Unk, Prn			
	Naso	nex			S	Nasal	2 Df, Qd			
	Naso	nex			S		Unk Unk, Qd			
	Olopa	atadine			S	Ophthalmic	Unk, Prn			
	Predi	nisolone			S	Unknown	Unk, Bid			
	Predi	nisolone			S	Unknown	Unk, Tid			
	Predi	nisolone			S	Unknown	Unk, Qid			
	Predi	nisolone			S	Unknown	Unk, Qd			
	Predi	nisolone			S	Unknown	2 Df, Qd			
	Predi	nisolone			S	Unknown	3 Df, Qd			
	Predi	nisolone			S	Unknown	4 Df, Qd			
	Predi	nisolone Teva			S	Unknown	50 Mg, Qd			
	Vigar	mox			S	Unknown	Unk, Tid			
	Vigar	nox			S	Ophthalmic	Unk, Tid			
	Besif	loxacin Hydrochloride			S	Ophthalmic	Unk Unk, Tid			
	Besif	loxacin Hydrochloride			S	Ophthalmic	Unk, Tid			
	Betax	xolol Hydrochloride			S	Ophthalmic	1 Df, Qd			
	Predi	nisone			S	Ophthalmic	50 Mg, Tid			
	Predi	nisone			S	Unknown	50 Mg, Qd			
FDA Received Date	Case #	Case Type	Health	Prof C	outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Apr-2018	14805741	NON-EXPEDITED				US-MYLANLAE 2018M1027315			Male	USA
Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Device Failure; No Adverse Event	Epipe	en Auto-Injector			S		Unk			Mylan



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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mf	r Control #	503B Facility	Age	Sex	Country
27-Apr-2018	14214063	EXPEDITED (15-DAY)	Hounn		LT	FR	-MYLANLABS-	ooo i domey	<u>v.An</u>	Female	FRA
Duefers d Terre	Doodee		0	0.70	D-I-		I7M1073455	<del>-</del>	Donathan		_
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	<u>Dos</u>	sage Text	<u>Duration</u>	Mf	<u>r</u>
Device Failure	Epipen				S		Uı	nk		M	ylan
FDA Received Date	Case #	Case Type	<b>Health</b>	<u>Prof</u>	Outcomes	Mf	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Apr-2018	13253927	EXPEDITED (15-DAY)			ОТ		-MYLANLABS- 17M1010570			Female	SWE
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dos	sage Text	<b>Duration</b>	Mf	<u>r</u>
Wrong Technique In	Epipen				S		Uı	nk		M	ylan
Product Usage Process	s Betapre	d			С		Uı	nk, Prn		M	ylan
	Zyrlex				С	Oral		aily Dose: 2 Df Dosage orm Every Days		M	ylan
	Tavegyl				С	Oral	2	Df, Unk		M	ylan
	Tavegyl Plavix				C C	Oral					ylan ylan
	Plavix Renitec				C C	Oral	10	Mg, Unk			ylan ylan
	Plendil				С	Oral				M	ylan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mf	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-May-2018	14790368	NON-EXPEDITED					-MYLANLABS- 18M1026797			Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTO	Role	Route	Dos	sage Text	<u>Duration</u>	Mf	<u>r</u>
Device Failure; Drug	Epipen Auto-Injector				S	Unknown	1	Unk, Unk		M	ylan
Ineffective; Pruritus; Swelling	Epipen Auto-Injector				S	Unknown				M	ylan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mf	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-May-2018	14841376	EXPEDITED (15-DAY)			НО		-MYLANLABS- 18M1028063			Unknown	GBR



Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mf	[	
Device Failure; Needle Epipen Junior Issue; No Adverse Event		S 0.15 Mg, Unk		lg, Unk	Mylan							
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
04-May-2018	14849338	NON-EXPEDITED				US-MYLA 2018M10	_			Female	USA	
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mf	<u>:</u>	
Dizziness; Heart Rate Increased	Epiper	1			S	Intramuscular	3 Mg,	Unk		M	/lan	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
04-May-2018	14849339	NON-EXPEDITED	US-MYLANLABS- 2018M1030577					Female USA				
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<b>Duration</b>	Mf	[	
Intentional Product Epipen Misuse; No Adverse Event			S Intramuscu				muscular			Mylan		
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
07-May-2018	14852493	NON-EXPEDITED			HO, LT, OT	US-PFIZE 20181803	-			Male	USA	
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mf	[	
Drug Ineffective	Epiper	<u> </u>			S	Unknown	Unk			Ur	nknown	
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
09-May-2018	14826234	EXPEDITED (15-DAY)			HO, LT	GB-MYLA 2018M10	-			Male	GBR	
Preferred Term	<u>Product</u>		Comp.	OTC	Role	Route	Dosage	e Text	<b>Duration</b>	Mf		
Device Failure; No Adverse Event	Epiper	Auto-Injector			S		Unk			M	/lan	



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2018	14869976	EXPEDITED (15-DAY)		0	Γ	US-MYLANL 2018M10293				Male	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective; Expire					S	Intramuscular	Unk N	⁄lg, Unk		M	ylan
Product Administered; Product Storage Error	Epipen				S	Intramuscular	Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-May-2018	14871723	EXPEDITED (15-DAY)		ОТ		US-MYLANLABS- 2018M1029979				Unknown	USA
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Injection Site Laceration; Epipen Jr. Auto-Injector Needle Issue				S					M	ylan	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>utcomes</u>	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-May-2018	14475272	EXPEDITED (15-DAY)		DE	E, OT	CA-MYLANL 2018M10067	-			Male	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mf	<u>r</u>
Death; Expired Device Used					S	Unknown	Unk			M	ylan
FDA Received Date	Case #	Case Type	Health	Prof Ou	utcomes	Mfr Contro	l#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-May-2018	14877409	EXPEDITED (15-DAY)		Н	O, OT	CA-MYLANL 2018M10309				Unknown	CAN
Preferred Term	Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>e Text</u>	<u>Duration</u>	Mf	<u>r</u>
Circumstance Or Information Capable O Leading To Medication Error; Drug Ineffective; Product Use Issue	1				S	Unknown				M	ylan